United States District Court
Northern District of California

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

VERINATA HEALTH, INC., et al.,

Plaintiffs,

v.

ARIOSA DIAGNOSTICS, INC, et al.,

Defendants.

Case No. 12-cv-05501-SI

ORDER RE POST-TRIAL MOTIONS, PLAINTIFF'S MOTION FOR A PERMANENT INJUNCTION, AND ADMINISTRATIVE MOTIONS TO SEAL

Re: Dkt. Nos. 648, 649, 650, 660, 661, 662, 666, 684, 697

Before the Court are the parties' post-trial motions (Dkt. Nos. 648, 649, 650, 661, 662, 666), plaintiffs' motion for a permanent injunction (Dkt. Nos. 660, 666), and two administrative motions to seal (Dkt. Nos. 684, 697). After hearing argument and considering the parties' materials, the Court rules as follows.

LEGAL STANDARD

I. Motion for judgment as a matter of law

"A renewed motion for judgment as a matter of law is properly granted only if the evidence, construed in the light most favorable to the nonmoving party, permits only one reasonable conclusion, and that conclusion is contrary to the jury's verdict." *Castro v. Cty. of Los Angeles*, 833 F.3d 1060, 1066 (9th Cir. 2016) (en banc) (quoting *Pavao v. Pagay*, 307 F.3d 915, 918 (9th Cir. 2002)) (internal quotation marks omitted), *cert. denied sub nom. Los Angeles Cty., Cal. v. Castro*, 137 S. Ct. 831 (2017) (Mem.). "A jury's verdict must be upheld if it is supported by substantial evidence, which is evidence adequate to support the jury's conclusion, even if it is also possible to draw a contrary conclusion." *Id.* (quoting *Pavao*, 307 F.3d at 918). In ruling on

such a motion, the trial court may not weigh the evidence or assess the credibility of witnesses in determining whether substantial evidence exists to support the verdict. *William Inglis & Sons Baking Co. v. ITT Cont'l Baking Co.*, 668 F.2d 1014, 1026 (9th Cir. 1981); *see also Mosesian v. Peat, Marwick, Mitchell & Co.*, 727 F.2d 873, 877 (9th Cir. 1984). "Substantial evidence is more than a mere scintilla." *Consol. Edison Co. v. NLRB*, 305 U.S. 197, 229 (1938); *Chisholm Bros. Farm Equip. Co. v. Int'l Harvester Co.*, 498 F.2d 1137, 1140 (9th Cir. 1974). Judgment as a matter of law is appropriate "when the jury could have relied only on speculation to reach its verdict." *Lakeside-Scott v. Multnomah Cty.*, 556 F.3d 797, 803 (9th Cir. 2009).

II. Motion for new trial

Federal Rule of Civil Procedure 59(a)(1) states, "[t]he court may, on motion, grant a new trial on all or some of the issues—and to any party—as follows: (A) after a jury trial, for any reason for which a new trial has heretofore been granted in an action at law in federal court . . . ." Fed. R. Civ. P. 59(a)(1). As the Ninth Circuit has noted, "Rule 59 does not specify the grounds on which a motion for a new trial may be granted . . . ." *Zhang v. Am. Gem Seafoods, Inc.*, 339 F.3d 1020, 1035 (9th Cir. 2003). Instead, the court is "bound by those grounds that have been historically recognized." *Id.* "Historically recognized grounds include, but are not limited to, claims 'that the verdict is against the weight of the evidence, that the damages are excessive, or that, for other reasons, the trial was not fair to the party moving.'" *Molski v. M.J. Cable, Inc.*, 481 F.3d 724, 729 (9th Cir. 2007) (quoting *Montgomery Ward & Co. v. Duncan*, 311 U.S. 243, 251 (1940)). The Ninth Circuit has held that "[t]he trial court may grant a new trial only if the verdict is contrary to the clear weight of the evidence, is based upon false or perjurious evidence, or to prevent a miscarriage of justice." *Passantino v. Johnson & Johnson Consumer Prods., Inc.*, 212 F.3d 493, 510 n.15 (9th Cir. 2000).

DISCUSSION

I. Ariosa's renewed motion for judgment as a matter of law and motion for a new trial on issues for which Ariosa bore the burden of proof (Dkt. No. 648)

Defendant Ariosa Diagnostics, Inc.[1] renews its motion for judgment as a matter of law ("JMOL") under Rule 50(b), and for a new trial under Rule 59, based on Ariosa's express license defense and the alleged invalidity of plaintiffs Illumina, Inc. and Verinata Health, Inc.'s patents. The background and procedural history of this case are described in the Court's Summary Judgment Order (Dkt. No. 517). As such, only portions of the record relevant to this motion are recounted here.

Plaintiff Verinata developed and offered non-invasive tests (such as the verifi® prenatal test) for the early identification of fetal chromosomal abnormalities. Dkt. No. 1 ¶ 11. Plaintiff Illumina develops, manufactures, and markets life science tools and integrated systems for large-scale analysis of DNA. Case No. 15-cv-2216, Dkt. No. 1 ¶ 4. Defendant Ariosa is a molecular diagnostics company that researches, evaluates, and develops non-invasive prenatal tests for chromosomal abnormalities in a fetus. Dkt. No. 283 ¶ 10.

This consolidated patent infringement action concerns the following patents: U.S. Patent Nos. 8,318,430 ("the '430 patent") and 7,955,794 ("the '794 patent"). Verinata owns the '430 patent, which is directed to methods for non-invasive prenatal screening of fetal chromosomal abnormalities. *See* '430 Patent. Illumina owns the '794 patent, which issued in June 2011 and is directed to methods for simultaneously detecting multiple target nucleic acids in a sample. *See* '794 Patent.

In January 2012, Ariosa and Illumina entered into a three-year Sale and Supply Agreement ("SSA"), under which Illumina agreed to supply specific consumables, hardware, and software to Ariosa. Dkt. No. 402-6. The SSA provided Ariosa with a non-exclusive license to Illumina's

[1] Roche Molecular Systems, Inc. bought Ariosa around December 2014. Roche was named a party during the course of this action, but was dismissed pursuant to stipulation. Roche was subsequently deemed a party to any judgment. Dkt. Nos. 375, 517. Ariosa was formerly known as Aria Diagnostics. Case. No. 11-cv-06391, Dkt. No. 1.

"Core IP Rights in Goods" in the "Customer Field of Use." *Id.* §§ 1, 3. "Core IP Rights in Goods" included "Illumina Intellectual Property Rights that pertain to the Goods (and use thereof in accordance with their Documentation) other than Secondary Illumina IP Rights in Goods[.]" *Id.* § 1. "Secondary IP Rights in Goods" was defined as "secondary Illumina Intellectual Property Rights that pertain to the Goods (and use thereof) only with regard to particular field(s) or application(s), and are not common to the Goods in all applications and fields. *Id.* "Customer Field of Use" was defined as "(a) commercial services for the cell-free detection of fetal chromosomal abnormalities having a length greater than one megabase by pre-natal screening using DNA sequencing, . . . and (b) internal, non-commercial experimental research[.]" *Id.*

Starting late 2012, plaintiffs filed a number of lawsuits accusing Ariosa's Harmony™ Prenatal Test of infringing the patents-in-suit. Dkt. No. 22; Dkt. No. 517 at 8-9. Two versions of the Harmony™ Prenatal Test were at issue—"Harmony V1" and "Harmony V2." Dkt. No. 517 at 6. Harmony V1 was made commercially available in 2012 and relied on sequencing (using Illumina sequencers) to obtain genetic data, while Harmony V2 was released in 2015 and relied on a microarray platform instead of sequencing. *Id.*; Dkt. No. 283 ¶ 12. The two versions used different protocols for processing the samples. Dkt. No. 416 at 3-7; Dkt. No. 517 at 6-7, 37. Verinata alleged Harmony V1 infringed the '430 patent, and Illumina alleged both Harmony versions infringed the '794 patent. Dkt. No. 349; Case Nos. 14-cv-1921, 15-cv-2216. Ariosa argued that the patents-in-suit were invalid and that it had an express license to the '794 patent. Dkt. No. 352; Case No. 14-cv-1921, Dkt. No. 68. Ariosa also asserted a counterclaim for breach of contract. Case No. 14-cv-1921, Dkt. No. 68.

The Court held a jury trial from January 8 to 25, 2018. On January 22, 2018, Ariosa filed a motion for JMOL under Rule 50(a) on Ariosa's defenses and affirmative counterclaims. Dkt. No. 618. Ariosa argued, *inter alia*, that no reasonable juror could find: that the '794 and '430 patents were not invalid; that the SSA did not grant Ariosa an express license to the '794 patent; or that Illumina did not breach the SSA by suing Ariosa. *Id.* The motions were denied without prejudice. On January 25, 2018, the jury returned a verdict, which found the '794 and '430 patents valid and infringed by Ariosa; found that Ariosa did not have an express license to the '794 patent under the

SSA; and found that Illumina did not breach the SSA by suing Ariosa. Dkt. No. 633. The jury awarded plaintiffs approximately $27 million in damages. *Id.* The Court entered judgment on January 29, 2018. Dkt. No. 642.

Ariosa moves for JMOL under Rule 50(b) and for a new trial under Rule 59 based on Ariosa's defenses and affirmative counterclaims. Dkt. No. 648. Ariosa argues that the jury's verdict on its licensing defense, affirmative counterclaims, and invalidity defenses is not supported by substantial evidence or is against the clear weight of evidence. *Id.*

A. Express license and breach of the SSA

The parties dispute whether the license to Illumina IP granted in the SSA encompassed the '794 patent. Ariosa contends that the Court should interpret the terms "Core IP Rights in Goods" and "Secondary IP Rights in Goods" in the SSA as a matter of law and argues that the '794 patent is not "Secondary IP," but rather is "Core IP," to which the SSA gave Ariosa a license. Dkt. No. 650 at 2-6. According to Ariosa, the Court should interpret "Illumina Intellectual Property Rights that pertain to the Goods," Dkt. No. 648 at 3 (quoting Ex. 615 (SSA) § 1.), to mean intellectual property rights that have "a connection with" Illumina's sequencing equipment. Dkt. No. 648 at 5. Ariosa points to the testimony of Illumina's expert witness, Dr. Cooper, who stated that Ariosa's use of an Illumina sequencer met the "detecting" limitation of the asserted '794 patent claims, as evidence that the '794 patent "has 'a connection with' Illumina's sequencing equipment and clearly fits within the definition of 'Core IP Rights in Goods.'" Dkt. No. 648 at 4-5. Ariosa argues that Illumina's position during trial, that "Core IP Rights" included only patents "inherent" in the use of Illumina's sequencers, is contrary to the language of the SSA. Dkt. No. 648 at 5-6.

Ariosa also argues that Illumina's interpretation of the SSA renders the grant of an express license under the SSA "nugatory" because under the doctrine of patent exhaustion, sale of Illumina's sequencer to Ariosa "automatically exhausted Illumina's right to enforce against Ariosa any patents that were inherently practiced in the use of those sequencers." *Id.* Ariosa argues that because of Ariosa's express license to the '794 patent through the SSA, Illumina was bound by a covenant not to sue Ariosa under the '794 patent. Dkt. No. 648 at 6. Thus, Ariosa contends that

Illumina breached the SSA by asserting the '794 patent against Ariosa. *Id.* Ariosa argues that there is "no conflicting extrinsic evidence" related to the interpretation of these terms because "the testimony of both sides' witnesses concerning their personal understanding of the meaning of the SSA is irrelevant under California law to the interpretation of the agreement." *Id.* at 2.

Illumina responds that whether it granted a license to the '794 patent under the SSA is a question of fact, and there was substantial evidence to support the jury's verdict finding that there was no such grant of license. Dkt. No. 672 at 10-11. Illumina argues that the trial evidence showed that the '794 patent related to the library prep product, which Ariosa did not buy, and not the sequencers; that the SSA gave Ariosa a license to use the sequencer, but not to use products that Ariosa did not purchase; that the SSA explicitly restricted Ariosa's right to "practice any patents supposedly exhausted by the sale of the goods"; and that the trial evidence demonstrated the '794 patent does not require the use of the Illumina sequencer to perform the detection step. *Id.* at 14-16. Illumina contends that even if the '794 patent were to pertain to "Goods," it would be "Secondary IP" excluded by the SSA. *Id.* at 16-17.

In California, a trial court employs a three-step process when the meaning of a contract term is disputed. *Wolf v. Walt Disney Pictures & Television*, 162 Cal. App. 4th 1107, 1126 (2008), *as modified on denial of reh'g* (June 4, 2008). "First, it provisionally receives any proffered extrinsic evidence that is relevant to prove a meaning to which the language of the instrument is reasonably susceptible." *Id.* (citations omitted). Second, if "in light of the extrinsic evidence, the language is reasonably susceptible to the interpretation urged, the extrinsic evidence is then admitted to aid the court in its role in interpreting the contract." *Id.* (citations omitted). Third, if "there is no material conflict in the extrinsic evidence, the trial court interprets the contract as a matter of law." *Id.* (citations omitted). "If, however, there is a conflict in the extrinsic evidence, the factual conflict is to be resolved by the jury." *Id.* at 1127 (citations omitted); *First Nat. Mortg. Co. v. Fed. Realty Inv. Tr.*, 631 F.3d 1058, 1067 (9th Cir. 2011) ("*Federal Realty*") ("As trier of fact, it is the jury's responsibility to resolve any conflict in the extrinsic evidence properly admitted to interpret the language of a contract.") (quoting *Morey v. Vannucci*, 64 Cal. App. 4th 904, 912-913 (1998)).

Furthermore, under California law, "[a] contract must be so interpreted as to give effect to the mutual intention of the parties" when they executed the contract. Cal. Civ. Code § 1636. Under the objective theory of contracts, "the objective intent, as evidenced by the words of the contract, rather than the subjective intent of one of the parties, . . . controls interpretation." *Founding Members of the Newport Beach Country Club v. Newport Beach Country Club, Inc.*, 109 Cal. App. 4th 944, 956 (2003). "The parties' undisclosed intent or understanding is irrelevant to contract interpretation." *Id.* However, a witness's own understanding of a contract may be relevant to its interpretation "when that understanding is not simply a private interpretation, but rather is founded in personal knowledge of the negotiations and the parties' expressed intent." *Onyx Pharm., Inc. v. Bayer Corp.*, 863 F. Supp. 2d 894, 897 (N.D. Cal. 2011) (citing *Fed. Realty*, 631 F.3d at 1068; *ASP Props. Grp. v. Fard, Inc.*, 133 Cal. App. 4th 1257, 1271 (2005)); *Pac. Gas & Elec. Co. v. G. W. Thomas Drayage & Rigging Co.*, 69 Cal. 2d 33, 39 (1968).

The trial testimony of witnesses who were parties to the SSA negotiations presented conflicting extrinsic evidence, rendering the factual dispute proper for a jury's consideration. Illumina's Mr. Naclerio and Ariosa's Dr. Stuelpnagel, for example, presented conflicting evidence of the relevant meaning given by the parties to the SSA's terms. Accordingly, because this trial testimony is relevant to interpreting the SSA so as to give effect to the mutual intention of the parties in forming and executing the SSA, the jury's verdict will stand. Defendant's motion is denied.

Mr. Naclerio, head of Illumina's corporate development from 2010 until 2016, presented testimony relevant to interpreting the meaning of the SSA's disputed terms. Naclerio testified that he was personally involved in the negotiation of the SSA and testified as to Illumina's express intent with regard to the SSA. Trial Tr. at 439:2-4 (**Q.** "Did you participate in discussions with Ariosa for a Supply Agreement?" **A.** "Yes."). Naclerio was responsible for corporate strategy, business development, negotiating acquisitions, divestitures, and investments with other companies before moving to Illumina Ventures, an investment fund targeting early-stage companies developing new products, primarily in the fields of genomics and precision medicine. *Id*. at 394:15-395:6. Naclerio stated Illumina's expressed intent was that Ariosa would simply

acquire the sequencer and not the library prep. Trial Tr. at 440:4-6. He testified, "the goal of these agreements was to convey the rights to the kind of commercial diagnostic testing in the NIPT field, and to make sure that we were giving them the rights to use our sequencer, but that we weren't giving up any other rights." *Id*. at 441:23-442:1.

Naclerio's testimony evidences Illumina's expressed intent to license solely the sequencer and not the library prep universe. *Id*. at 449:23-450:1 ("I would be surprised if it was their expectation that they were getting rights to sample prep by buying the sequencer. It just doesn't pass the common sense test."). Contradicting Ariosa's assertions, Illumina's intent was limited in scope. *Id*. at 444:16-18. ("[W]e're giving you the sequencer. You can develop your own stuff with it; but we're not giving you anything else. That was the idea."). Naclerio noted that rights pertaining to the goods were intended to mean "rights to the goods in this case is the sequencer. And we're saying that you have the right to use the sequencer to sequence." *Id*. at 445:2-4. When asked whether Illumina intended to convey the rights to use the library prep selection step, Naclerio stated, "[C]learly not." *Id*. at 445:8. Naclerio's testimony makes clear that in Illumina's view, the SSA defined Core IP as related to the product being purchased (i.e., the sequencer), not Core IP in other products, and that all other Secondary IP were excluded from Core IP. *Id*. at 449:23-450:1.

Dr. John Stuelpnagel, Ariosa's founder and Executive Chairman, presented conflicting evidence that is relevant to understanding the SSA. *Id*. at 777:13-15 (**Q.** "In terms of the negotiating team for the Sale and Supply Agreement, that was your general counsel, Ms. DeVore and Ken Song and yourself; is that correct?" **A.** "Correct"). According to Dr. Stuelpnagel, Ariosa's view was that the terms of the SSA created, "without any doubt, that Ariosa would have 'Freedom to Operate,' with using Illumina Core IP Rights." *Id*. at 778:24-779:1.[2] Dr. Stuelpnagel stated that the '794 patent was Core IP and was included in the license obtained in the SSA. *Id*. at 809:24-810:1 (**Q.** "Now, did this agreement cover any patent licenses from Illumina to Ariosa?"

[2] Mr. Naclerio confirmed that "'Freedom to Operate' means they're saying they, in their view, had freedom to do what they were planning to do without infringing other folks' IP . . . ." Trial Tr. at 522:20-23.

A. "It did."). According to Dr. Stuelpnagel, Core IP Rights are defined as "intellectual property rights held by Illumina [that] gives [Ariosa] a license to those Illumina Intellectual Property Rights that we need to use the goods, which is the sequencing, and consumables, and/or pertains or relates to the goods. And so it's anything associated with performing that test." *Id.* at 810:7-11. Dr. Stuelpnagel's testimony evidenced his belief and Ariosa's expressed intent that the Core IP Rights in Goods at the time of the SSA included the following: "Illumina's intellectual property rights that pertain—relate—to the goods, and use thereof, in accordance with their documentation, other than secondary Illumina IP rights." *Id.* at 811:9-12. Dr. Stuelpnagel elaborated that "if Illumina held intellectual property—intellectual property means patents and patent applications, and other things—if they owned those, we had the right to use those, if they were sort of general purpose and required to use the sequencer and the sequencing reagents." *Id.*

The trial testimony demonstrated that the SSA is reasonably susceptible to conflicting interpretations and contradictory expressed intent. The testimony of Mr. Naclerio and Dr. Stuelpnagel presented conflicting extrinsic evidence founded in personal knowledge of the negotiations and are evidence of the relevant meaning that the parties gave to the terms of the SSA. Accordingly, the Court properly submitted the question of whether the '794 patent fell within "Core IP Rights in Goods" under the SSA to the jury. *Id.* at 1866:5-15. Defendant's motion on express licensing is DENIED.

B. Invalidity of the '794 and '430 patents

Ariosa argues that at least the clear weight of evidence is against the jury's findings that the '794 patent was not invalid as anticipated by U.S. Patent Application No. 09/333,110 ("Straus") under 35 U.S.C. § 102, and that the '430 patent was not invalid for lack of enablement under Section 112. Dkt. No. 648 at 7-15.

Under the Patent Act, each claim of a patent is presumed to be valid, and the "burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." 35 U.S.C. § 282. To overcome the presumption of validity, a defendant must prove

invalidity by clear and convincing evidence. *Microsoft Corp. v. I4I Ltd. P'ship*, 564 U.S. 91, 95 (2011).

1. Anticipation of the '794 patent by Straus

As a threshold matter, Illumina argues that Ariosa is barred from challenging the '794 patent under the doctrine of assignor estoppel because Drs. Stuelpnagel and Oliphant are inventors of the '794 patent, they assigned their rights to the patent to Illumina, and they are in privity with Ariosa. Dkt. No. 672 at 2; Dkt. No. 661. The Court agrees with Illumina. As is discussed more fully in part IV, below, the Court finds that assignor estoppel applies to Ariosa and that the asserted claims of the '794 patent are within the scope of the rights assigned by Drs. Stuelpnagel and Oliphant to Illumina. Accordingly, Ariosa's invalidity defense against the '794 patent must fail. *See Diamond Sci. Co. v. Ambico, Inc.*, 848 F.2d 1220, 1224 (Fed. Cir. 1988). However, even if assignor estoppel did not bar Ariosa from challenging the validity of the '794 patent, the Court finds there was substantial evidence at trial to support the jury's findings on this issue.

Ariosa argues its expert, Dr. Cantor, presented "unrebutted testimony" that Straus disclosed all elements of the asserted '794 patent claims. Dkt. No. 648 at 7. Ariosa also contends that Illumina's expert, Dr. Cooper, made "legally spurious" assertions at trial that for there to be anticipation of the '790 patent, Straus must disclose all elements of the claim in one disclosure or figure, such as Figure 5. *Id.* Ariosa points to Dr. Cooper's testimony contending that Straus's disclosure of three claim elements[3] ("at least 100 different target sequences," "more than 100

[3] Claim 1 of the '794 patent is representative, and recites, in part: 1. A multiplex method for determining whether a sample contains at least 100 different target sequences, comprising:

a) providing a sample which may contain at least 100 different single-stranded target sequences attached to a first solid support;

b) contacting said target sequences with a probe set comprising more than 100 different single-stranded probes, wherein each of said more than 100 different probes comprises:

i) a first universal priming site, wherein each of said more than 100 different probes has identical universal priming sites, and

ii) a target specific domain, such that different double-stranded hybridization complexes are formed, each of the different hybridization complexes comprising one of said more than 100 different single-stranded probes and one of the different single-stranded

different single stranded probes," and "identical universal priming sites") in the specification "should be disregarded" for not being "expressly linked to Figure 5." *Id.* Ariosa argues that, even though the Court properly instructed the jury on an anticipation standard that is "[c]onsistent with settled law," the jury erroneously credited Dr. Cooper's theory of anticipation when it found the '794 patent was not anticipated by Straus. *Id.* at 8, 10-11.

Illumina responds that Dr. Cantor's testimony fell short of showing by clear and convincing evidence that Straus discloses "identical universal priming sites," and that Dr. Cooper provided testimony rebutting Dr. Cantor. Dkt. No. 672 at 3-4. Illumina argues that Dr. Cooper did not misstate the legal standard for anticipation. *Id.* at 4-6.

A prior art reference anticipates a claim if "it discloses all the claimed limitations 'arranged or combined in the same way as in the claim.'" *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed. Cir. 2015) (citations omitted). The disclosure of a prior art reference may not be limited to a preferred embodiment. *Arthrocare Corp. v. Smith & Nephew, Inc.*, 406 F.3d 1365, 1372 (Fed. Cir. 2005) (citing *Ultradent Prod., Inc. v. Life-Like Cosmetics, Inc.*, 127 F.3d 1065, 1068 (Fed. Cir. 1997)). Rather, a prior art reference may anticipate a claim "if a person of skill in the art, reading the reference, would 'at once envisage' the claimed arrangement or combination" even without express disclosure of "all the limitations arranged or combined as in the claim." *Kennametal*, 780 F.3d at 1381 (citing *Application of Petering*, 301 F.2d 676, 681 (C.C.P.A. 1962)).

The Court finds that a reasonable jury could find Ariosa did not prove by clear and convincing evidence that Straus anticipated the '794 patent. Ariosa's expert, Dr. Cantor, testified at trial that Straus disclosed each and every element of the asserted claims of the'794 patent. Trial Tr. at 1467:9-1476:7. In particular, Dr. Cantor relied on Straus's Figure 5, which disclosed "almost everything" needed to demonstrate how Straus disclosed every element of the claims. *Id.* at 1466:1-5. Dr. Cantor explained that Figure 5 did not disclose all the elements of the asserted claims, including the limitation of "100 different probes [having] identical universal priming sites"

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target sequences from the sample;
c) . . . . Dkt. No. 172-2.

in claim 1. *See id.* at 1471:1-4. Thus, Dr. Cantor relied on, *inter alia*, the disclosure of "a single pair of amplification sequences" found elsewhere in Straus. *Id.* Illumina's expert, Dr. Cooper, testified that Straus did not make "clear" that the elements of the claimed method identified by Dr. Cantor by "dancing around the document" should be done "all together." Trial Tr. at 1654:7-17, 1654:25-1655: *see* Trial Tr. at 1599:10-1600:11.

In view of the conflicting evidence, the jury was entitled to assess the credibility of each party's experts to determine whether Straus disclosed all elements of claim 1 "arranged or combined in the same way as in the claim."[4] *See i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 848 (Fed. Cir. 2010), *aff'd*, 564 U.S. 91 (2011) (denying defendant's motion for judgment as a matter of law on its invalidity defense because "the jury heard conflicting testimony" and was "free to disbelieve [the defendant's] expert" in evaluating the evidence).

Ariosa also argues that it was prejudiced when plaintiffs repeatedly raised the IPR proceedings during trial. Illumina contends that it did not specifically refer to IPR proceedings, nor did Ariosa object when Illumina allegedly made the "prejudicial" references to the IPR proceedings.

Although Illumina made reference to the *inter partes* review proceedings during trial, the Court finds that either the reference fell within the exceptions set forth in the Court's pre-trial order, or was not so prejudicial as to require a new trial on that basis.[5] Regardless, assignor

[4] Dr. Cooper's statement that "all elements of the claim have to be in one disclosure or figure," Trial Tr. at 1599:4-9, was a less than accurate statement of the legal standard for anticipation, but was not prejudicial. Dr. Cooper clarified in later testimony that disclosure in a single figure was not a requirement for finding anticipation, and Ariosa acknowledges that the jury instructions provided the correct legal standard. *See* Trial Tr. at 1648:12-18, 1655:2-5; Dkt. No. 648 at 8 (citing Trial Tr. at 1863:1-5).

[5] The Court granted Ariosa's motion *in limine* to preclude reference to post-grant proceedings at the PTO, with the following exceptions: (i) To provide context to the contract counterclaims, plaintiffs may present neutral evidence, not including outcomes, regarding "other patent proceedings" or "other patent challenges" that Ariosa referenced during the parties' negotiations. If plaintiffs seek to introduce the outcome of any proceeding, they must seek and obtain specific permission from the Court in advance. (ii) As to prior art included by Ariosa in its IPR petition but as to which the proceedings were not initiated, Ariosa is not precluded by estoppel from pursuing invalidity on such prior art. However, if Ariosa "either expressly or implicitly, leads the jury to believe that this is the first time the relevant references have been evaluated, the Court will permit [plaintiffs] to rebut this line of argument[.]" *Rembrandt Wireless Techs., LP v. Samsung Elecs. Co.*, No. 13-cv-213, 2015 U.S. Dist. LEXIS 20306, at *19 (E.D.

estoppel precludes Ariosa from challenging the '794 patent. Accordingly, the Court DENIES Ariosa's motion for judgment as a matter of law, or for new trial, on its defenses.

2. Enablement of the '430 patent

Ariosa argues the evidence at trial showed that the '430 patent does not meet the enablement requirement because the patent fails to disclose an algorithm for "determining the presence or absence of a fetal aneuploidy" in the context of a targeted sequencing approach as claimed.[6] Dkt. No. 648 at 12. Ariosa contends one of ordinary skill in the art would not be able to adapt known algorithms designed for analyzing random shotgun sequencing data for use on targeted sequencing data without undue experimentation. *Id.* at 13-15. Ariosa also argues evidence showed that the patent failed to disclose necessary steps to eliminate "noise" in the data to detect fetal DNA, or any examples showing that the claimed pooling and indexing worked as

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Tex. Jan. 31, 2015). (iii) Plaintiffs may request to introduce specific portions of the post-grant proceedings. Dkt. No. 547 (Final Pretrial Scheduling Order) at 6-7.

[6] Claim 1 of the '430 patent is representative, and recites in part:

1. A method for determining a presence or absence of a fetal aneuploidy in a fetus for each of a plurality of maternal blood samples . . . comprising fetal and maternal cell-free genomic DNA, said method comprising:

(a) obtaining a fetal and maternal cell-free genomic DNA sample . . . ;

(b) selectively enriching a plurality of non-random polynucleotide sequences of each fetal and maternal cell-free genomic DNA sample of (a) to generate a library . . . , wherein said plurality of non-random polynucleotide sequences comprises at least 100 different non-random polynucleotide sequences selected from a first chromosome tested for being aneuploid and at least 100 different non-random polynucleotide sequences selected from a reference chromosome, wherein the first chromosome tested for being aneuploid and the reference chromosome are different . . . [;]

(c) pooling the libraries generated in (b) to produce a pool of enriched and indexed fetal and maternal non-random polynucleotide sequences;

(d) performing massively parallel sequencing of the pool . . . to produce sequence reads corresponding to enriched and indexed fetal and maternal non-random polynucleotide sequences…. ;

(e) . . . enumerating sequence reads corresponding to enriched and indexed fetal and maternal non-random polynucleotide sequences . . . ; and

(f) . . . determining the presence or absence of a fetal aneuploidy comprising using a number of enumerated sequence reads corresponding to the first chromosome and a number of enumerated sequence reads corresponding to the reference chromosome of (e).

Dkt. No. 64-7.

intended. *Id.* at 12. Lastly, Ariosa claims that "Verinata never actually reduced the alleged invention of the '430 patent to practice or used it in any of its own tests." *Id.* at 12-13 (citing Trial Tr. at 262:15-23, 349:1-5, 351:7-9, 1481:13-17.).

Illumina responds that Ariosa's expert, Dr. Cantor, testified there were prior art references "adequately" disclosing the elements of claim 1, and that Dr. Rava, an inventor of the '430 patent, and Dr. Cooper, Illumina's expert, testified that the patent referenced other patents that disclosed statistical methods to determine fetal aneuploidy. Dkt. No. 672 at 8-10. Illumina argues that Dr. Cooper testified that Ariosa itself used algorithms for analyzing random shotgun sequencing data in its proof of concept study of its Harmony assay. *Id.* at 10.

Section 112 of the Patent Act requires a patent specification to "contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same . . . ." 35 U.S.C. § 112 ¶1. "To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *MagSil Corp. v. Hitachi Glob. Storage Techs., Inc.*, 687 F.3d 1377, 1380 (Fed. Cir. 2012) (citations omitted). Factors relevant for determining whether undue experimentation is required include the following: (1) "the quantity of experimentation necessary"; (2) "the amount of direction or guidance presented"; (3) "the presence or absence of working examples"; (4) "the nature of the invention"; (5) "the state of the prior art"; (6) "the relative skill of those in the art"; (7) "the predictability or unpredictability of the art"; and (8) "the breadth of the claims." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

"Enablement is a question of law based on underlying factual findings." *MagSil*, 687 F.3d at 1380 (citing *In re Wands*, 858 F.2d at 735). Where the enablement inquiry is factual in nature, "it is amenable to resolution by the jury." *BJ Servs. Co. v. Halliburton Energy Servs., Inc.*, 338 F.3d 1368, 1371 (Fed. Cir. 2003) (citing *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1533 (Fed. Cir. 1987)). In reviewing a jury finding based on its factual determinations, courts must "look to whether a reasonable jury could have made the underlying factual findings necessary to provide substantial evidence in support of its conclusion." *Id.* at 1371-72 (citing

Allen Organ Co. v. Kimball Int'l, Inc., 839 F.2d 1556, 1566 (Fed. Cir. 1988)); *accord Dow Chem. Co. v. Nova Chems. Corp. (Canada)*, 809 F.3d 1223, 1226 (Fed. Cir. 2015).

The Court finds a reasonable jury could have weighed the facts presented at trial to provide substantial evidence supporting its finding that Ariosa failed to show, by clear and convincing evidence, that the '430 patent was not enabled. Specifically, there was no dispute as to the amount of guidance provided by the '430 patent regarding the algorithm for "determining the presence or absence of a fetal aneuploidy" because the '430 patent specification does not explicitly disclose such an algorithm. Trial Tr. at 344:18-23, 345:12-19. There was no dispute that the '430 patent claims recite a directed or "nonrandom" sequencing approach to detect fetal aneuploidy from a maternal blood sample. *Id.* at 321:13-322:12, 349:6-12. It was also undisputed that the specification incorporates by reference publications that disclose known statistical methods for determining fetal aneuploidy based on random sequencing techniques. *Id.* at 344:24-345:3.

The trial testimony confirms there was conflicting evidence concerning how much experimentation would have been necessary for one of ordinary skill in the art to adapt these previously known methods used for random sequencing data to the targeted sequencing approach as claimed.[7] For instance, Ariosa's witness, Dr. Wang, testified as to the technical "challenges" Ariosa faced when developing an algorithm for analyzing targeted sequencing data to detect fetal aneuploidy in maternal blood. *Id.* at 1343:23-1348:6. Dr. Wang testified that Ariosa tried a "Z score" method, which "didn't work as well" and was rejected for use in the Harmony test. *Id.* at 1347:17-1348:6. In addition, Dr. Cantor testified that the algorithms for random shotgun sequencing described in the publications referenced in the '430 patent "definitely won't work" without "improv[ing] on them," and that the patent "wouldn't have helped me in the slightest" to make a targeted sequencing approach work. *Id.* at 1480:19-1481:12.

By contrast, Dr. Rava, a witness for Illumina, testified that the algorithms for random

[7] There was no dispute over the remaining *Wands* factors on this issue. There was no dispute over the '430 patent's disclosure of working examples of the determining step, the state of the prior art for analyzing sequencing data, the skill of those in the art of sequencing data analysis, the predictability of sequencing data analysis, or the breadth of claim 1 of the '430 patent.

shotgun sequencing described in the publications referenced in the '430 patent "could be very similar to the ones that would be use[d] in a directed sequencing approach" but "would have to be optimized." Trial Tr. at 344:24-345:11. Finally, Dr. Cooper testified that the references cited in the '430 patent describe statistical methods ("Bayesian likelihood method," "Z score") that were similar to those used by Ariosa for "non-invasive detection of Trisomy 21 and 18 using selective sequencing of cell-free DNA from specific chromosomes." Trial Tr. at 1617:8-1621:1.

The Court finds a reasonable jury could have weighed the conflicting evidence and made a factual determination as to the amount of experimentation that would have been required for one skilled in the art to perform step 1(f). The Court also finds that the jury was "provide[d] substantial evidence in support of its conclusion" as to enablement of the '430 patent. *See Halliburton Energy*, 338 F.3d at 1371-72.

Ariosa argues that the inventor's failure to reduce to practice the invention claimed in the '430 patent "is strong evidence that the specification lacks enablement." Dkt. No. 648 at 12-13 (citing *Ormco Corp. v. Align Tech., Inc.*, 498 F.3d 1307, 1319 (Fed. Cir. 2007)).[8] The Court is unconvinced, and finds *Ormco* distinguishable from the present facts. In *Ormco*, the Federal Circuit affirmed the district court's summary judgment order finding certain claims of the asserted patents invalid for lack of enablement. *Ormco*, 498 F.3d at 1318-19. The patents at issue related "to the computer-aided design and manufacture of custom orthodontic appliances," and the claims were "construed to require automatic computer determination of the finish positions of the teeth without human adjustment of the final results." *Id.* at 1311, 1317. The district court was unconvinced by the inventors' testimony stating that the patentee's products "incorporated the automatic determination aspect of the invention." *Id.* at 1318. The district court was unconvinced because one of the inventors testified that the patentee "never attempted to create a computerized

[8] Ariosa also relies on *Old Town Canoe Co. v. Confluence Holdings Corp.*, 448 F.3d 1309 (Fed. Cir. 2006) for the proposition that an expert witness's inability to perform a claimed method "supports a claim of nonenablement." Dkt. No. 648. However, the *Old Town Canoe* court held that such evidence raised an issue of material fact to be resolved by a jury, and thereby reversed the district court's grant of the patentee's motion for judgment as a matter of law on enablement of the asserted patent. *Old Town Canoe*, 448 F.3d at 1313, 1320. Here, the jury was presented with Dr. Cantor's expert opinion on the insufficiency of the '430 patent disclosure for enablement and was entitled to weigh it in arriving at the verdict. *See* Trial Tr. 1479:5-1481:12.

system that automatically determined tooth positions without human decision making" and that, while full automation "was a goal . . . , variations in human anatomy had prevented the attainment of that goal." *Id.* The patentee presented "[n]o convincing countering evidence." *Id.* The *Ormco* court concluded "[i]f an inventor attempts but fails to enable his invention in a commercial product that purports to be an embodiment of the patented invention, that is strong evidence that the patent specification lacks enablement." *Id.*

Here, there is no evidence that the '430 patent inventors attempted and failed to enable the invention. First, Dr. Rava's inability to recall creating a "full algorithm" for analyzing the sequencing data alone is insufficient to show that the inventors attempted and failed to enable the invention. *See* Trial Tr. at 349:1-5. The evidence suggests the inventors did develop a method of analyzing the sequencing data because Dr. Rava testified that while developing the targeted approach described in the '430 patent, there "would have been a method" to "determin[e] from the [sequencing] results that we were getting whether or not we could differentiate between the aneuploidy samples and the non-aneuploidy samples" using "a lot of analysis in Excel spreadsheets." *See id.* at 348:15-25.

Nor does the fact that Verinata's prenatal testing product does not embody the invention claimed in the '430 patent demonstrate that the '430 patent inventors "attempt[ed] but fail[ed] to enable [their] invention in a commercial product that purports to be an embodiment of the patented invention." *See Ormco*, 498 F.3d at 1318. Dr. Rava testified that Verinata "decided that we wanted to [commercialize their prenatal testing product using] the whole genome approach, so that we could get information from across the genome," *rather than* use the targeted approach described in the '430 patent. *See id.* at 326:6-15, 349:1-5.

Ariosa also relies on *Union Pacific Resources Company v. Chesapeake Energy Corporation*, 236 F.3d 684 (Fed. Cir. 2001) to argue that because the '430 patent fails to enable any and all ways for determining aneuploidy using a nonrandom sequencing approach, "the full scope of the claims is thus indisputably not enabled." *See* Dkt. No. 648 at 14. This reliance is misplaced. In *Chesapeake Energy*, the Federal Circuit affirmed the district court's findings that the asserted patent was not enabled because the claimed method required a step involving

"significant mathematical manipulation" of input data but the specification failed to disclose how to achieve such a "pivotal" process. 236 F.3d at 691. The asserted patent claimed "a particular method of horizontal drilling for the exploration of oil and natural gas" and disclosed "a method for locating a drill bit in a horizontal borehole relative to the surrounding strata." *Id.* at 688. However, the patent did not disclose how to "rescale" or "correlate" certain input data as required by the claimed methods because the patentee "kept as a trade secret the computer programs designed to perform the rescaling step." *Id.* at 690. Moreover, the *Chesapeake Energy* court noted the correlation process was recognized by the patentee's expert as being "probably the most unique part of the patent." *Id.* at 691.

Here, in contrast, there was conflicting evidence as to whether the step of analyzing the sequencing data was "pivotal" to the invention claimed in the '430 patent. As discussed above, there was conflicting evidence regarding whether the '430 patent's reference to previously-described methods for analyzing random sequencing data to determine fetal chromosome aneuploidy was sufficient to teach one skilled in the art to perform data analysis in the context of a targeted sequencing approach. Dr. Rava, an inventor of the '430 patent, did not deny that the determining step of the claimed method on its own was not novel, and testified that the known algorithms could be used to perform the determining step with "some optimization." Trial Tr. 347:1-349:12. The Court finds that the jury could weigh the conflicting testimonies to provide substantial evidence supporting its verdict. Accordingly, defendant's motion on invalidity is DENIED.

II. Ariosa's renewed motion for judgment as a matter of law and motion for a new trial on issues for which plaintiffs bore the burden of proof (Dkt. No. 649)

Defendant moves for JMOL under Rule 50(b), and for a new trial under Rule 59 based on non-infringement and patent damages. Dkt. No. 649. Defendant argues that the jury's verdicts on infringement of the '794 and '430 patents and on damages are not supported by substantial evidence, or are against the clear weight of evidence. *Id.*

A. Non-infringement

Defendant moves for judgment as a matter of law, or for a new trial, on non-infringement on the grounds that plaintiffs failed to meet their burden to prove by a preponderance of the evidence that Harmony V1 and V2 perform each step of the asserted claims of the '794 patent, or that Harmony V1 performs each step of the asserted claims of the '430 patent.

Determining whether an accused product infringes a patent involves a two-step analysis: "First, the claim must be properly construed to determine its scope and meaning. Second, the claim as properly construed must be compared to the accused device or process." *Carroll Touch, Inc. v. Electro Mech. Sys., Inc.*, 15 F.3d 1573, 1576 (Fed. Cir. 1993) (citations omitted). Claim construction is a matter of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 970-71 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). "The determination of infringement, whether literal or under the doctrine of equivalents, is a question of fact." *Ecolab, Inc. v. Envirochem, Inc.*, 264 F.3d 1358, 1364 (Fed. Cir. 2001); *Int'l Rectifier Corp. v. IXYS Corp.*, 361 F.3d 1363, 1369 (Fed. Cir. 2004) ("Comparison of the claims to the accused [product] requires a factual determination that every claim limitation or its equivalent is found in the accused [product]."), *subsequent mandamus proceeding sub nom. In re IXYS Corp.*, 148 F. App'x 933 (Fed. Cir. 2005). "Direct infringement of a method claim requires all steps of the claimed method to be performed by or attributable to a single entity." *LifeNet Health v. LifeCell Corp.*, 837 F.3d 1316, 1325 (Fed. Cir. 2016). "The patent owner has the burden of proving infringement and must meet its burden by a preponderance of the evidence." *Cradle IP, LLC v. Texas Instruments, Inc.*, 5 F. Supp. 3d 626, 636 (D. Del. 2013) (citing *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988)), *aff'd*, 588 F. App'x 1000 (Fed. Cir. 2015).

1. Harmony V2

Claim 1 of the '794 patent is representative, and recites in relevant part:

> 1. A multiplex method for determining whether a sample contains at least 100 different target sequences, comprising:

a) providing a sample which may contain at least 100 different single-stranded target sequences attached to a first solid support;

b) contacting said target sequences with a probe set comprising more than 100 different single-stranded probes, wherein each of said more than 100 different probes comprises:

i) a first universal priming site . . . , and

ii) a target specific domain, such that different double-stranded hybridization complexes are formed, each of the different hybridization complexes comprising one of said more than 100 different single-stranded probes and one of the different single-stranded target sequences from the sample;

c) removing unhybridized probes;

d) contacting said probes of the hybridization complexes with a first enzyme and forming different modified probes;

e) contacting said modified probes with:

i) at least a first primer that hybridizes to said universal priming site;

ii) NTPs; and

iii) an extension enzyme;

wherein said different modified probes are amplified and forming different amplicons;

f) immobilizing said different amplicons to a second solid support, and

g) detecting said different amplicons immobilized to said second solid support, thereby determining whether the sample contains at least 100 different target sequences."

U.S. Patent No. 7,955,794 col. 68 l. 44-col. 69 l. 12.

Defendant argues that no reasonable juror could find that Harmony V2 performs steps 1(a), 1(b) in the claimed order, or steps 1(f) and 1(g). Dkt. No. 649.

a. The '794 patent: Steps 1(a) and 1(b)

Defendant contends that the trial evidence failed to show Harmony V2 performs the "providing" (step 1(a)) before the "contacting" (step 1(b)) as required by the claims because plaintiffs' expert, Dr. Cooper, testified that in Harmony V2, the beads (solid support) are added after the probes for hybridization. *Id.* at 1-2. Defendant argues that it "does nothing" to contact single-stranded target sequences attached to a solid support with a probe set. *Id.* Plaintiffs

respond that Dr. Cooper's testimony explained to the jury that during the Harmony V2 assay, there would be "a lot more than 100 single-stranded target sequences" in the reaction vessel at the end of the hybridization reaction, after which the solid support is added, and that therefore, Harmony V2 "inevitably" performs steps 1(a) and 1(b). *Id.*

A method "is defined as 'an act, or a series of acts.'" *Kaneka Corp. v. Xiamen Kingdomway Grp. Co.*, 790 F.3d 1298, 1305 (Fed. Cir. 2015) (citing *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *In re Kollar*, 286 F.3d 1326, 1332 (Fed. Cir. 2002) ("A process . . . consists of doing something, and therefore has to be carried out or performed.")); *see NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1318 (Fed. Cir. 2005) ("[T]he use of a process necessarily involves doing or performing each of the steps recited."), *abrogated on other grounds, see IRIS Corp. v. Japan Airlines Corp.*, 769 F.3d 1359, 1361 n.1 (Fed. Cir. 2014).

Here, the parties contest whether Harmony V2 follows the order of the steps in the '794 patent for steps 1(a) and 1(b). To uphold a jury verdict of infringement, a court must find that there was "substantial evidence" i.e., if "there is evidence upon which a reasonable jury could have found infringement." *Ultradent Prods., Inc. v. Life-Like Cosmetics, Inc.*, 127 F.3d 1065, 1070 (Fed. Cir. 1997). For infringement cases, "[w]here the evidence of infringement consists merely of one experts opinion, without supporting tests or data, the district court is under no obligation to accept it." *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 842 F.2d 1275, 1280 (Fed. Cir. 1988).

In *Garlock*, the Federal Circuit noted that whether an imprecise claim limitation is literally met is a question of fact for the trial court. Specifically, the court noted that, when construing the disputed meaning of the term "about," the correct determination was not the meaning assigned by the parties but rather "dependent on the factual situation presented." *Garlock*, 842 F.2d at 1280. The Federal Circuit noted, "[t]he only evidence on this point was the opinion testimony of Gore's expert that his estimated rate of 76.5% per second to 139% per second was 'about 100% per second' which the district court did not accept as proving infringement." *Id.*. The Federal Circuit affirmed. *Id*. at 1281-82. The instant case is distinguishable from *Garlock*. In *Garlock*, there was no mention that proffered expert testimony relied upon any theoretical foundation for the notion

that the estimated rate was about 100% per second. Here, Dr. Cooper's conclusion relies upon scientific principles and scientific theory. As a result, the instant case is analogous to *Ultradent*.

In *Ultradent*, the Federal Circuit held that theoretical evidence provided by an expert can fulfill the substantial evidence requirement. *See Ultradent*, 127 F.3d at 1070. In *Ultradent*, the plaintiff needed to prove that defendant's products contained "about 3.5% to about 12% by weight carboxypolmethylene defined as a slightly acidic vinyl polymer with active carboxyl groups." *Id.* There, the plaintiff's expert, Dr. Yost, testified that in his opinion defendant's products infringed. Dr. Yost based his explanation on a theoretical foundation, noting that "in solution, the ions are free to move around" and that "the hydrogen ions are free 'to dissociate and reassociate with the carboxyl group.'" *Id*. The court concluded that Dr. Yost's theoretical foundations were sufficient to fulfill the substantial evidence standard. *Id.*, 127 F.3d at 1070 ("Dr. Yost's testimony constitutes substantial evidence of infringement, and for purposes of the motion for a new trial, we cannot say that the district court committed a manifest abuse of discretion in ruling that the great weight of the evidence was not against the verdict."). Just as the parties in *Ultradent* were "in agreement that the only evidentiary basis upon which the jury could have reached the result it did is the testimony of Ultradent's expert witness, Dr. Yost," the jury here must have relied on Dr. Cooper's theory to find that infringement occurred. *Id.*

Dr. Cooper's testimony is similarly based on theoretical foundations. Dr. Cooper's assertion that in Harmony V2, at least 100 different single stranded target-sequences are left over after the two hour period of temperature reduction (and that they first hybridize to the solid support before annealing to the probes) is based on probability and scientific theory. Dr. Cooper explained that first, the earlier portions of the reaction at 70 degrees occur above the melting point of the probes, meaning that the hybridization of the target sequences to the probes only has an opportunity to occur in the latter portion of the process. Trial Tr. at 966:1-8. The jury could have reasonably inferred that this increases the chances of 100 different single-stranded target sequences being present after two hours.

Dr. Cooper also opined that there are billions of cell-free DNA fragments (some of which contain a target sequence and others of which do not), 6,800 types of target sequences, and over

20,000 different types of probes. *See Id*. at 965:10-13; 966:14-19. According to Dr. Cooper, because there are so many probes and fragments, they collide with one another and decrease the chances that the probes will hybridize to the proper target sequences within the first two hours. *Id*. at 966:25-967:1-4. The probes can only hybridize if they attach to a complementary single-stranded target sequence. *Id*. 966:20-24. Dr. Cooper testified that, even if one percent of the fragments remained un-hybridized and therefore single stranded, then there would be at least 100,000 different single-stranded DNA fragments left over. *Id*. at 967:15-21. Accordingly, by sheer number and probability, there would be at least 100 different single-stranded target sequences. *Id.*

Dr. Cooper also explains how the solid support first attaches to 100 different single-stranded target sequences and how the target sequences then hybridize to the probes. According to Dr. Cooper, after two hours, the solid support is added and the process is "allow[ed] continued time to proceed." *See* Trial Tr. 464:4-8, 465:1-4. The solid support streptavidin beads can then quickly attach to the target sequences when they are added because of streptavidin's properties and the interactions with biotin-coated cell-free DNA fragments. Trial Tr. 951:14-25-952:1-3. Dr. Cooper testified that the reaction is nonspecific and the strongest covalent reaction known on the order of 10^{-15}. *Id*. at 952:12-14. Given the additional time to proceed following the addition of the solid support, there is still ample time for the 100 single-stranded target sequences (attached to the beads) to hybridize to their respective three probes. *Id*. at 964:9-965:4; (Hearing Tr. 6/8/2018; p. 21 Ariosa's Slides).

Just as the Federal Circuit in *Ultradent* found that expert testimony based on scientific theory fulfilled the requirement for substantial evidence, this Court finds that Dr. Cooper's testimony, founded upon scientific theory, "constitutes substantial evidence of infringement." *See Ultradent* at 1070. That Ariosa presented conflicting evidence is not enough to conclude Dr. Cooper's testimony is not substantial. As the Federal Circuit held in *Ultradent*, there was substantial evidence of infringement despite the defendant's presentation of conflicting evidence.

See Id. at 1070. In sum, this Court upholds the jury's finding of infringement of steps 1(a) and 1(b) of Harmony V2.[9]

b. The '794 patent: Steps 1(f) and 1(g)

Defendant contends that evidence at trial failed to show Harmony V2 performs steps 1(f) and 1(g) because Harmony V2 uses "readout cassettes," which are "indisputably different," or at least substantially different, from the claimed "amplicons." Dkt. No. 649 at 10, 12. Defendant argues that Harmony V2 does not detect immobilized amplicons, and asks the Court to reconsider its ruling on claim construction regarding step 1(f) ("immobilizing said different amplicons"). *Id.* at 10-15. Defendant argues that plaintiffs did not present "particularized testimony" required to support their DOE theory and relied on "conclusory and irrelevant testimony." *Id.* at 12-15. Plaintiffs respond that whether Ariosa's "readout cassettes" qualified as the claimed "amplicons" was a question of fact for the jury; that Ariosa admitted that it uses "cleaved amplicons"; and that there was detailed testimony describing the insubstantial difference between a readout cassette and an amplicon. Dkt. No. 670 at 7-10.

The Federal Circuit has ruled that "[w]hen addressing the doctrine of equivalents, a court must ask whether an asserted equivalent is an 'insubstantial difference' from the claimed element, or whether it matches the 'function, way, and result of the claimed element.'" *Epos Techs. Ltd. v. Pegasus Techs. Ltd.*, 766 F.3d 1338, 1348 (Fed. Cir. 2014) (citing *Deere & Co. v. Bush Hog, LLC*, 703 F.3d 1349, 1356 (Fed. Cir. 2012) (quoting *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997)). A party may invoke DOE against the producer of the device "if it performs substantially the same function in substantially the same way to obtain the same result." *Graver Tank & Mfg. Co. v. Linde Air Prod. Co.*, 339 U.S. 605, 608 (1950). The Supreme Court

[9] Having heard and considered the trial testimony in this case, this Court is no longer convinced that its claim construction determination regarding the order of steps 1(a) and 1(b) of the '794 patent was correct, or that its preclusion of Illumina from presenting Doctrine of Equivalents evidence about the order of steps was correct. However, all parties tried the case based on the Court's prior orders, and these motions are likewise evaluated based on those prior orders.

has clarified DOE, stating that "the doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole." *Warner-Jenkinson*, 520 U.S. at 29.

The Court agrees with plaintiffs and finds there was substantial evidence to support the jury's implicit finding that Ariosa performs steps 1(f) and 1(g) of the '794 patent when using "readout cassettes" to perform the Harmony V2 test, at least under the doctrine of equivalents. There was no dispute that in Harmony V2, modified probes are amplified to produce amplicons, and the amplicons are modified to produce the readout cassettes, which are then immobilized. Trial Tr. at 1074:17-1078:10 (Dkt. No. 603), 1398:7-1403:14 (Dkt. No. 598). There was conflicting evidence as to whether by using the readout cassettes, Ariosa was carrying out substantially the same function as steps 1(f) and 1(g) of claim 1, in substantially the same way, to achieve substantially the same result. Ariosa's witness Dr. Quackenbush testified that amplicons were substantially different from readout cassettes because the former "didn't work" but the latter did work, giving "much better accuracy, [and] much higher quality results" for Harmony V2. Trial Tr. at 1402:14-25 (Dkt. No. 598). Dr. Oliphant testified similarly, explaining that immobilizing amplicons was "not useful" and "doesn't work" in the context of Harmony V2. *Id*. at 178:7-10 (Dkt. No. 603).

In contrast, Dr. Cooper testified that immobilizing the readout cassettes and immobilizing the amplicons serve substantially the same function of "immobiliz[ing] onto a solid support"; the immobilizing is done in substantially the same method of "hybridization of [the] DNA molecule"; and achieves substantially the same result of "detection of the target sequences that were in the original mixture." *Id*. at 1682:6-1683:1; *see* Trial Tr. at 979:21-985:22 (Dkt. No. 603). In view of the trial testimony, the Court finds the jury's verdict should not be disturbed. Defendant's motion is DENIED.

2. **Harmony V1**

a. The '794 patent: Steps 1(a) and 1(b)

Defendant argues that no reasonable juror could find Harmony V1 performs steps 1(a) and 1(b) of the '794 patent because the evidence shows Harmony V1 does not perform the steps in the

claimed order. Dkt. No. 649 at 1. Defendant contends the evidence shows that in Harmony V1, "the probes and solid support are added simultaneously to the sample containing target sequences." *Id.* Plaintiffs respond that in the reaction mixture, the single-stranded target sequences attach to the solid support before the probes hybridize. Dkt. No. 670 at 11-12.

This Court's claim construction determined that there is an order for the steps of the '794 patent; for claim 1, "providing" must occur before "contacting." Trial Tr. at 1855:6–13. Accordingly, the relevant inquiry is whether adding the probe, target sequences, and solid support simultaneously, as Harmony V1 does, literally infringes the steps 1(a) and 1(b) of the '749 patent. *See* '794 Patent at claim 1; *Kaneka,* 790 F.3d at 1306.

Plaintiffs presented evidence that it did. Even adding the probes, target sequences and solid support simultaneously, Harmony VI still causes the steps in the '794 patent in first "providing" target sequences (with attached solid support) and then "contacting" the targeted sequences with the probes. There is an active step or performance of "providing" in the form of raising the temperature to 70 degrees, which allows at least 100 single-stranded sequences to be attached to the solid support. *See* Trial Tr. (1/16/2018) at 960:2-961:7. Afterwards, there is an active step of "contacting" in the form of decreasing the temperature from 70 degrees to 30 degrees, as this allows hybridization between the probe and the target sequences (that are already attached to the solid support). *Id*. at 962:2–962:5 (Dkt. No. 603). Harmony V1, therefore, directly follows the order (of "providing" and then "contacting") and content of claims 1(a) and 1(b).

Plaintiff's expert, Dr. Cooper explained that the melting point of 70 degrees does not allow probes to hybridize to the target sequences, whereas the target sequences are much more likely to attach to the solid support due to their inherent properties. Trial Tr. (1/16/2018) at 955:4–955:25 (Dkt. No. 603). In addition, the binding of the target sequences (through biotin) and the solid support (through streptavidin) is the strongest known non-covalent interaction. Trial Tr. (1/18/2018) at 1439:21–1440:2 (Dkt. No. 598).

The designer of Harmony V1, Dr. Oliphant, confirmed Dr. Cooper's position. Dr. Oliphant stated that the attachment of the solid support to the target sequences occurs first before the hybridization of the target sequences to the probes when stating that "[w]e attempt to—to

attach all of the cell-free DNA to the beads," and that the "next step in the process" was to "hybridize the locus-specific oligonucleotides." Trial Tr. (1/16/2018) at 1091:10–1092:8 (Dkt. No. 603). Given the testimony from Dr. Cooper and Dr. Oliphant, the jury's verdict was not against the great weight of the evidence and the jury could reasonably conclude that the simultaneous addition in Harmony V1 is an insubstantial difference.

Accordingly, the evidence presented at trial is sufficient to support the jury's finding of infringement since the simultaneous addition of the solid support, probes, and target sequences in Harmony V1 does not prevent steps 1(a) and 1(b) from occurring in the order specified by the Court.

b. The '430 patent: Step (f)

Claim 1 of the '430 patent is representative, and recites in relevant part:

> 1. A method for determining a presence or absence of a fetal aneuploidy in a fetus for each of a plurality of maternal blood samples . . . comprising fetal and maternal cell-free genomic DNA, said method comprising:
>
> (a) obtaining a fetal and maternal cell-free genomic DNA sample . . . ;
>
> (b) selectively enriching a plurality of non-random polynucleotide sequences of each fetal and maternal cell-free genomic DNA sample of (a) to generate a library . . . , wherein said plurality of non-random polynucleotide sequences comprises at least 100 different non-random polynucleotide sequences selected from a first chromosome tested for being aneuploid and at least 100 different non-random polynucleotide sequences selected from a reference chromosome, wherein the first chromosome tested for being aneuploid and the reference chromosome are different . . . [;]
>
> (c) pooling the libraries generated in (b) to produce a pool of enriched and indexed fetal and maternal non-random polynucleotide sequences;
>
> (d) performing massively parallel sequencing of the pool . . . to produce sequence reads corresponding to enriched and indexed fetal and maternal non-random polynucleotide sequences . . . ;
>
> (e) . . . enumerating sequence reads corresponding to enriched and indexed fetal and maternal non-random polynucleotide sequences . . . ; and
>
> (f) . . . determining the presence or absence of a fetal aneuploidy comprising using a number of enumerated sequence reads corresponding to the first chromosome and a number of enumerated sequence reads corresponding to the reference chromosome of (e).
>
> Dkt. No. 64-7.

According to the Court's claim construction, the term "comprising" "means including, but not limited to," and the term "reference chromosome" refers to "a chromosome different from the particular chromosome that is being tested for aneuploidy." Trial Tr. at 1854:17–18, 1855:3–5.

Ariosa argues no reasonable juror could find that Harmony V1 performs step 1(f) of the '430 patent because Harmony V1 does not determine the presence or absence of a fetal aneuploidy using "enumerated sequence reads" or a "reference chromosome." Dkt. No. 649 at 16-19. Ariosa points to evidence showing Harmony V1 uses "quantile normalization" derived from median sequence counts pooled from multiple samples, and argues any enumerated sequence reads are "eliminated" in the process. *Id.* at 17. Illumina points to evidence showing Harmony V1 uses sequence counts as the original input before transforming the data. Dkt. No. 670 at 13-14. Illumina also contends trial evidence showed Harmony V1 "uses sequence reads from chromosome 13 and 18 as references" when testing chromosome 21. *Id.* at 14-15.

Here, the Court finds that there is at least conflicting evidence properly before the jury, and there was substantial evidence to support the verdict. The claims of the '430 patent require only that enumerated sequence reads be used to determine the presence or absence of fetal aneuploidy, and the use of such reads from "a" reference chromosome. The claims do not say the enumerated sequence reads cannot be transformed or normalized, and do not exclude using the test chromosome "in the denominator" as argued by Ariosa.

B. Damages

Defendant argues that Illumina has not provided evidence to support an award of damages, pointing to its "unintended, *de minimis* infringement"; Illumina's failure to apportion damages to exclude the value of non-patented features in the Harmony tests; and Illumina's presenting a "skewed [] damages horizon" by including lost royalty payments, convoyed sales and revenue from plaintiffs' foreign subsidiaries in its lost profit calculation. Dkt. No. 649 at 19-25. Plaintiffs respond that the jury awarded an amount that was closer to the value presented by defendant's damages expert ($3.3 million) than that offered by plaintiffs' expert ($104.5 million), and therefore the jury "reached a middle ground" that took into account both parties' arguments. Dkt.

No. 670 at 16-17. Plaintiffs argue defendant's infringing conduct was "commercial in nature" and all of the Harmony tests are infringing, and therefore the infringement is far from *de minimis*. *Id.* at 18-19. Plaintiffs contend that the jury did apportion, and there is no evidence that the jury awarded lost profits, convoyed sales, or lost profits from foreign subsidiaries. *Id.* at 19-24.

The Federal Circuit has stated that "[i]n reviewing damages awards in patent cases, we give broad deference to the conclusions reached by the finder of fact," and that "a jury's damages award 'must be upheld unless the amount is grossly excessive or monstrous, clearly not supported by the evidence or based only on speculation or guesswork.'" *Monsanto Co. v. McFarling*, 488 F.3d 973, 981 (Fed. Cir. 2007) (quoting *Monsanto Co. v. Ralph*, 382 F.3d 1374, 1383 (Fed. Cir. 2004)). Consequently, the Court gives deference to the jury's verdict in its analysis. *See also Ericsson, Inc. v. Harris Corp.*, 352 F.3d 1369, 1379 (Fed. Cir. 2003) (affirming denial of JMOL for damages because the award was supported by substantial evidence though "[t]he jury obviously did not accept [plaintiff's] theory of price erosion damages in its entirety, as it awarded only $645,000 of the $8.1 million that [plaintiff] requested."); *Monsanto Co. v. Ralph*, 382 F.3d 1374, 1383 (Fed. Cir. 2004) ("The jury's award of damages is entitled to deference[.]"); *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1580 (Fed. Cir. 1992) ("[T]he jury's finding must be upheld unless the amount is "grossly excessive or monstrous," clearly not supported by the evidence, or based only on speculation or guesswork.").

In the present case, Illumina's expert calculated $104.5 million in damages, while Ariosa's expert calculated $3.3 million. Trial Tr. at 1197:2-9; at 1546:6-7. The Court finds that is it clear the jury did not wholesale accept the theory of Illumina's damages expert, given that that the jury only awarded approximately $27 million of the $104 million that plaintiffs requested. Dkt. 633 at 6-7. Accordingly, while the Court moves through an analysis of damages below, it gives deference to the jury's findings.

1. Whether every Harmony V2 test infringes

Ariosa argues the damages were improperly awarded because there is no evidence every Harmony V2 test infringes. Dkt. No. 649 at 19-20. Specifically, Ariosa repeats its prior argument

that there is not substantial evidence to support Dr. Cooper's claim of infringement regarding steps 1(a) and 1(b) of the '794 patent by Harmony V2. *Id*. Illumina responds that Ariosa waived the argument because Ariosa did not present it at trial or in the pre-verdict JMOL motion. Assuming the argument was not waived, Illumina argues that there is substantial evidence of infringement from Dr. Cooper's testimony, and because that evidence is based on the conditions that Ariosa uses for every sample it runs, every Harmony V2 test infringes. Dkt. No. 670 at 17-18. This Court finds there is substantial evidence to support the jury's verdict that Harmony V2 infringes the '794 patent. Accordingly, Ariosa's argument is DENIED.

2. *De Minimis* argument

Ariosa argues the jury's finding of infringement regarding steps 1(a) and 1(b) of the '794 patent are unintended and *de minimis* because at least 100 target sequences attaching to the solid support before hybridizing to the probes does not add value. Dkt. No. 649 at 20-21. Ariosa contends that as a result, damages were improperly calculated. *Id*. Illumina argues that Ariosa waived its *de minimis* argument because it did not present it at trial or in its pre-verdict JMOL motion. Dkt. No. 670 at 18. Furthermore, Illumina argues Ariosa cannot show whether the jury considered *de minimis* infringement in the damages calculation. *Id*. Illumina further contends that the jury determined the importance of the 100 different target sequences by deciding that Ariosa infringed on the '794 patent and then awarding Illumina damages for that infringement. Finally, Illumina contends that Dr. Cooper explained more than 100 single-stranded target sequences would be present, thus negating the *de minimis* argument. *Id*. at 18-19.

The Court disagrees with Ariosa's *de minimis* infringement argument. *De minimis* infringement has been "'very narrowly' construed, providing a 'defense to infringement performed for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.'" *Nichia Corp. v. Seoul Semiconductor Co.*, No. C-06-0162 MMC, 2007 WL 2428040, at *6 (N.D. Cal. Aug. 22, 2007) (quoting *Embrex, Inc. v. Serv. Engineering Corp.*, 216 F.3d 1343, 1349 (Fed.Cir.2000)). Here, the Harmony V1 and Harmony V2 tests were used for more than amusement, idle curiosity,

or philosophical inquiry. Ariosa sold Harmony V1 and currently markets Harmony V2. As a result, this Court is not persuaded by Ariosa's argument of unintended, *de minimis* infringement.

In addition, even if the infringement of steps 1(a) and 1(b) of the '794 patent is *de minimis* (the jury has already acknowledged the value of the steps), the infringement was not limited to steps 1 (a) and 1(b). Ariosa admitted that the jury considered infringement of steps 1(f) and 1(g), and the jury verdict mentions infringement of claims 2, 3, 9, and 13 as well. *See* Dkt. No. 633 at 2-3. The jury could have determined the value of the infringement based on those claims.

3. Failure to apportion

Ariosa argues that plaintiffs failed to properly apportion damages because their calculations included patented and non-patented components. Illumina counters that substantial evidence supports the "apportioned amount" the jury awarded. Illumina also argues that Ariosa fails to demonstrate this is not what the jury did, and fails to show the jury did not consider apportionment.

A patent expert must "apportion value between the patented features and the vast number of non-patented features contained in the accused products. *Virnetx, Inc. v. Cisco Sys*., Inc., 767 F.3d 1308, 1329 (Fed. Cir. 2014); *see also Exmark Mfg. Co. Inc. v. Briggs & Stratton Power Prod. Grp., LLC*, 879 F.3d 1332, 1351 (Fed. Cir. 2018) (finding that an expert must apportion damages and sufficiently tie the royalty rate to the facts of the case).

a. Royalty rate or royalty base

Ariosa argues that Illumina's damages expert, Mr. Malackowski, did not adjust his proposed royalty to account for Harmony's non-patented features. Dkt. No. 649 at 22-23. Illumina responds that Malackowski accounted for non-infringing features through his selection of the royalty rate instead of the royalty base. Dkt. No. 670 at 19-20.

The Federal Circuit has ruled that damages can be apportioned properly "by adjustment of the royalty rate so as to discount the value of a product's non-patented features." *Exmark*, 879 F.3d at 1348 (citing *Ericsson, Inc. v. D–Link Sys., Inc.*, 773 F.3d 1201, 1226 (Fed. Cir. 2014).

Consequently, the first issue before the Court is whether Malackowski accounted for non-infringing features through the royalty rate.

Malackowski did not quantitatively reduce the royalty rate. Trial Tr. at 1259:8-14. However, he claimed to have used the *Georgia-Pacific f*actors to qualitatively reduce the royalty rate. *Id*. at 1259:8-14. The Federal Circuit has ruled that apportionment can be carried out through "a proper analysis of the *Georgia-Pacific* factors." *Exmark*, 879 F.3d at 1348. Accordingly, the next issue before the Court is whether Malackowski properly adapted those factors.

According to the Federal Circuit, "a 'superficial recitation of the *Georgia-Pacific* factors, followed by conclusory remarks, [cannot] support the jury's verdict.'" *Exmark*, 879 F.3d at 1350 (citing *Whitserve, LLC v. Comput. Packages, Inc.*, 694 F.3d 10, 31 (Fed. Cir. 2012)). Moreover, "[w]hen performing a *Georgia-Pacific* analysis, damages experts must not only analyze the applicable factors, but also carefully tie those factors to the proposed royalty rate." *Id*. The Federal Circuit wrote the following:

> Exmark's expert acknowledged that other elements of the mowers affect sales and profits of the mowers, including durability, reliability, brand position, dealer support, and warranty. But she failed to conduct any analysis indicating the degree to which these considerations impact the market value or profitability of the mower and therefore impacted her suggested 5% royalty rate.

Exmark, 879 F.3d at 1350 (Fed. Cir. 2018).

Malackowski touched on the *Georgia-Pacific* factors during trial. For example, when speaking about *Georgia-Pacific* factor four, Malackowski stated "that we heard Mr. Bird testify that he would be unwilling to license that competitor. And so that's a consideration that would increase, everything else being equal, what the royalty would pay." Trial Tr. at 1189:20-23. Aside from his statement concerning increase, Malackowski does not explain how the increase led to his conclusion of obtaining five percent royalty rate for the '794 patent. *Id.* at 1191:21-22. When discussing the factors as a whole, Malackowksi stated that "in some cases it's just we need to reduce the price, because our comparables had things our hypothetical wouldn't, and in some cases it suggests we had to increase the price." *Id*. at 1189:6-10.

While this Court finds that Malackowski's assertions are relatively generalized, the Court defers to the jury's verdict for two primary reasons. First, the Court notes that the jury award reflects approximately one quarter of plaintiffs' proposed damages award. Second, the Court is not convinced that the jury did not discount Malackowksi's calculations for non-accused features. Accordingly, the jury's verdict stands.

b. Hypothetical sale price

Ariosa also argues that Malackowski used the incorrect value of $761 to calculate his royalty base, and that the value should have been halved since Ariosa ultimately only received half of the amount. Dkt. No. 649 at 23. Illumina responds that Ariosa waived its argument by not including it in its pre-verdict JMOL motion. Dkt. No. 670 at 22. Assuming Ariosa did not waive its argument, Illumina argues that Ariosa represented it would sell Harmony for $700 to $800. *Id.* at 22.

The Federal Circuit has ruled that "[t]he determination of a reasonable royalty, however, is based not on the infringer's profit margin, but on what a willing licensor and licensee would bargain for at hypothetical negotiations on the date infringement started." *State Indus., Inc. v. Mor-Flo Indus., Inc.*, 883 F.2d 1573, 1580 (Fed. Cir. 1989) (citing *Radio Steel & Mfg. Co. v. MTD Prod., Inc.*, 788 F.2d 1554, 1557 (Fed.Cir.1986)).

In 2012, the parties contractually agreed on a royalty through the Sale and Supply Agreement ("SSA"). *See* Trial Tr. at 461:8-9. Ariosa agreed to pay a three percent royalty to Illumina, which Illumina "intended to be [based] on" the sale price of the Harmony test. Trial Tr. at 461:22-462:2. Subsequent to the SSA, Ariosa entered into a distribution agreement with LabCorp, in which LabCorp would distribute the Harmony test and Ariosa would receive approximately half of that sale price. Trial Tr. at 462:3-7. As a result, Ariosa sought to adjust its three percent royalty fee with Illumina to reflect the new, lower value it was receiving for the Harmony test.

Illumina's Mr. Naclerio testified as to the parties' 2012 arrangement:

> And, you know, pretty much as soon as we signed this, there was—there was some contention over—for example, we ended up with a three percent test fee in here, which we intended to be on the price of the test, which—which, when we negotiated this, it was our understanding that they were going to sell the test directly. After we signed this, they signed a deal with LabCorp where LabCorp essentially was the distributor. And then they sort of said, well, we—our arrangement with LabCorp is we get, I think, 3–or $400 upfront, add up the 7–or $800, and so we think we should only pay you on the 3–or 400.

Trial Tr. at 461:22-462:7. As Naclerio's testimony demonstrates, Ariosa initially represented that it would sell the test for $700 to $800, and that Illumina "intended" the "three percent test fee . . . to be [based] on the price of the test." *See* Trial Tr. at 461:22-462:7, 1262:16-1263:15. It was only after signing a deal with LabCorp that Ariosa attempted to modify the three percent test fee. Trial Tr. at 462:3-7.

The Court finds the relevant value for calculating the royalty base is the original figure. Illumina's intention to charge the test fee was based on the original $700 to $800 value. This calculation was closer in time to the day infringement began. Malackowski testified "that Illumina/Verinata, in the negotiation, would say, look, you can charge whatever you, want, but we're not going to let you pay us a royalty because you decide to drop the price in half, our royalty gets cut in half." Trial Tr. at 1193:4-8. Malackowski also explained that "in a hypothetical, if you're licensing your technology, you're not going to let the buyer get away with deciding how they're going to split up their revenue to pay less on a percentage." Trial Tr. at 1263:12-15.

Naclerio and Malackowski's testimony supports the notion that Illumina hypothetically would have bargained to receive a percentage on the $761 on the date infringement began. Based on their testimony, the jury could have reasonably concluded that the royalty base should properly be calculated based on the hypothetical selling price of $761.

c. Skewed damages regarding lost profits

The Federal Circuit has stated the following regarding lost profits:

> To recover lost profits, the patent owner must show "causation in fact," establishing that "but for"' the infringement, he would have made additional profits. When basing the alleged lost profits on lost sales, the patent owner has an initial burden to show a reasonable probability that he would have made the asserted sales "but for" the

> infringement. Once the patent owner establishes a reasonable probability of "but for" causation, the burden then shifts to the accused infringer to show that [the patent owner's "but for" causation claim] is unreasonable for some or all of the lost sales.

Grain Processing Corp. v. Am. Maize-Prod. Co., 185 F.3d 1341, 1349 (Fed. Cir. 1999) (internal quotations and citations omitted).

Malackowski explained that there were three components in his lost profits calculations: "sales, test fees, and reagents." Trial Tr. at 1169:6-9.

i. Lost test fees

Ariosa argues that Malackowski improperly attempted to categorize lost test fees as part of lost profits despite the fact that plaintiffs' own construction of them was as lost royalties. Dkt. No. 649 at 24. Ariosa argues that lost royalties cannot fall under lost profits. As a result, Ariosa argues that Illumina should not be awarded the lost test fees. *Id*. According to Ariosa, because Illumina's damages expert construed test fees incorrectly and caused the jury to calculate them as lost profits, the jury award was improper. *Id*.

Plaintiffs argue that Ariosa has not proven that the jury awarded lost profits. Dkt. No. 670 at 22. In addition, according to plaintiffs, precedent dictates that lost royalties can still be awarded under lost profits; therefore, the lost test fees can properly be included under lost profits even if the lost test fees are categorized as lost royalties. *Id*. at 22–23. Plaintiffs also contend that, even if precedent is not in their favor, the lost test fees are not royalties because the supply agreements say otherwise. *Id*. at 23.

The Federal Circuit provided guidance regarding lost royalties and lost profits in *Warsaw Orthopedic, Inc. v. NuVasive, Inc.*, 778 F.3d 1365, 1376 (Fed. Cir. 2015). Warsaw, the patentee, licensed its patented technology to related companies. *Id*. Warsaw argued that defendant's infringing conduct "detrimentally affected those manufacturers' sales, which in turn negatively affected the royalty payments they made to Warsaw." *Id.* Warsaw, therefore, contended that it was entitled to lost royalties under a lost profits award. *Id*. The Federal Circuit disagreed and brought attention to the following rule:

> To be entitled to lost profits, we have long recognized that the lost profits must come from the lost sales of a product or service the patentee itself was selling. As we explained in *Rite-Hite*, "[n]ormally, if the patentee is not selling a product, by definition there can be no lost profits."

Id. (quoting *Rite–Hite*, 56 F.3d at 1548 (Fed. Cir. 1995)). The Federal Circuit then held that the patentee could not recover lost royalties.[10]

Malackowski testified that plaintiffs' lost test fees encompassed two parts, valued together at approximately $75. *See* Trial Tr. at 1109:9-22; 1153:1-10. First, the number included a license to the NIPT patent pool rights; second, it included a license for the rights to use Illumina equipment. *Id*. at 1109:20-22 ("One, it's a license for the rights to use this IP; but it also conveys the rights to use our actual products, themselves, in the field of NIPT."). Much like the patentee in *Warsaw* who was only licensing and not practicing a patent, Illumina is only in the business of licensing as related to the lost test fees. *Id*. at 1109:9-22. Illumina, therefore, cannot recover the lost test fees under lost profits.

However, Ariosa cannot show that the jury awarded Malackowski's supposed lost profits calculation. Although Malackowski included the test fees in the lost profits calculation, the jury instructions only state, "[i]n this case, Illumina and Verinata seek to recover lost profits for some of Ariosa's sales of its Harmony™ Prenatal Test product, and a reasonable royalty on the rest of Ariosa's sales."[11] Dkt. No. 625 at 22. The jury verdict does not explain how the jury came to its calculations. Because the jury could have discounted lost test fees in its lost profits award, the jury's verdict stands in relation to sales regarding lost test fees.

ii. Convoyed reagent sales

Ariosa argues that Malackowski should not have included "reagent sales to the third parties who compete with Ariosa" as part of his damages calculation because the sequencing reagents are

[10] Here, the parties contest whether the lost test fees are lost royalties. *See* Dkt. No. 649 at 24; Dkt. No. 670 at 23. Regardless, it is undisputed that Malackowski classified the lost test fees as lost profits. *See* Trial Tr. at 1169:6-9. As a result, the analysis from *Warsaw* is still applicable.

[11] Malackowski testified that the test fees fall under his "lost profits" calculation. It is possible that the jury was convinced by this and calculated the test fees as lost profits in their damages award.

not a functional unit with the patent itself. Dkt. No. 649 at 24-25. Illumina responds that there is no evidence the jury took into account convoyed reagent sales when calculating the damages. Dkt. No. 670 at 23. Assuming the jury did take into account the sale, Illumina argues that the reagents pertain to the '794 patent because the reagents are used to run the sequencers which Ariosa used for Harmony V1 (which the jury found infringed the '794 patent). *Id*. at 24.

The Federal Circuit has held that "[a] patentee may recover lost profits on unpatented components sold with a patented item, a convoyed sale, if both the patented and unpatented products 'together were considered to be components of a single assembly or parts of a complete machine, or they together constituted a functional unit.'" *Am. Seating Co. v. USSC Grp., Inc.*, 514 F.3d 1262, 1268 (Fed. Cir. 2008) (citing *Rite–Hite Corp. v. Kelley Co.*, 56 F.3d 1538, 1550 (Fed. Cir. 1998)). The Federal Circuit in *American Seating Company* elaborated that "[o]ur precedent has not extended liability to include items that have essentially no functional relationship to the patented invention and that may have been sold with an infringing device only as a matter of convenience or business advantage." *Am. Seating*, 514 F.3d at 1268 (citing *Rite–Hite*, 56 F.3d at 1550). At trial, when discussing the '794 patent, Illumina stated that the '794 patent "doesn't pertain to the Goods. It's not about the sequencer." Trial Tr. at 1918:20-21. Given that the '794 patent is not about the sequencer, then they can function independently of one another, and the functional unit requirement is not fulfilled.

Still, Ariosa fails to show that the jury did not discount the convoyed reagent sales. The verdict form does not specify, and Ariosa only speculates that the jury considered the sales. In addition, because the jury awarded approximately $27 million instead of $104 million, the Court is persuaded that Ariosa's argument concerning convoyed reagent sales does not warrant JMOL or a new trial.

iii. Foreign subsidiaries

Ariosa argues that the jury was misled by the lost profits calculations because Malackowski took into account revenues of Illumina's foreign subsidiaries. Dkt. No. 649 at 25. Illumina contends that Malackowski's calculations only factored into account damages lost by

U.S. entities that are parties to the case, not foreign subsidiaries. Dkt. No. 670 at 24. Ariosa contends there is no evidence that the "foreign portion of [Ariosa's] sales would have been earned by the domestic Illumina or Verinata entities that were parties to this action." Dkt. No. 680 at 15.

When calculating the lost profits, Malackowski took into account all of Ariosa's sales, although only three-fifths of the sales were made in the United States. *See* Trial Tr. 1214:19-23. The Supreme Court recently ruled on the topic of recovering lost profits from foreign sales. *WesternGeco LLC v. ION Geophysical Corp.*, 138 S. Ct. 2129 (2018).

In *WesternGeco*, the infringer "manufactured the components for its competing system in the United States and then shipped them to companies abroad." *Id*. at 2135. The court found that this constituted a "domestic act of supplying the components that infringed WesternGeco's patents." *Id*. at 2138. The Supreme Court thus held that the patentee could recover lost foreign profits under 35 U.S.C. § 284 and 35 U.S.C. § 271(f)(2).

The Supreme Court considered the Patent Act § 284 and § 271(f)(2) and applied the second step of the two-step inquiry in relation to the presumption of extraterritoriality. The second step states that "'[i]f the conduct relevant to the statute's focus occurred in the United States, then the case involves a permissible domestic application' of the statute, 'even if other conduct occurred abroad.'" *Id*. at 2137 (quoting *RJR Nabisco, Inc. v. European Cmty.*, 136 S. Ct. 2090, 2101 (2016)). 35 U.S.C. § 284 states that "[u]pon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement." 35 U.S.C. § 271(f)(2) states the following:

> Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

The Supreme Court determined that the focus of Section 284 is infringement. Moreover, the Supreme Court determined that the focus of § 271(f)(2) is the act of "suppl[ying] in or from

the United States." *Id*. at 2138. The Supreme Court held that, considering the focus of the two statutes, § 271(f)(2) and § 284 in conjunction allow the patent owner to recover for lost foreign profits.

Illumina similarly asserts a damages claim under Section 284 of the Patent Act. Just as the infringing act of supplying components in *WesternGeco* was domestic, Ariosa's infringement occurred in the United States. Specifically, Malackowski explained that the infringement occurred in the United States in the following statements: "because *all of the tests are processed in California*, all of Ariosa's tests; therefore they're all infringing. Both of these companies have their headquarters in the U.S., and then serve a global market." Trial Tr. at 1213:13-17 (emphasis added). The Court finds Malackowski's argument persuasive and holds that the focus inquiry is satisfied.

Nevertheless, precedent dictates that there must be a causal nexus between the lost profits and the infringement. *See Grain Processing Corp. v. Am. Maize-Prod. Co.*, 185 F.3d 1341, 1349 (Fed. Cir. 1999). For instance, in *WesternGeco*, "WesternGeco proved that it had lost 10 specific survey contracts due to ION's infringement." *WesternGeco*, 138 S. Ct. at 2135. Illumina has the burden to prove it would have received profits in foreign countries but for Ariosa's infringement, which it did not do. Accordingly, Illumina presented insufficient evidence of "but for" infringement.

In the end, however, Ariosa cannot show that the jury took into account any revenues from foreign subsidiaries in their damages, especially given that the jury only awarded $27 million of the requested $104 million.

III. Ariosa's motion for judgment under Rule 52 (Dkt. No. 650)

Ariosa moves for judgment on partial findings under Rule 52 (c). Dkt. No. 650. Ariosa contends that Illumina is equitably estopped from obtaining relief on claims of infringement of the '794 patent by Harmony V1 because trial evidence demonstrated that Illumina, through statements, omissions, and other conduct it engaged in, misled Ariosa into reasonably believing

that Illumina would not sue Ariosa over the '794 patent; and that Ariosa's investments in the development and commercialization of its Harmony tests were made in reasonable and detrimental reliance on such statements, omissions, and conduct. *Id.* at 2:7-3:8.

Federal Rule of Civil Procedure 52(c) allows a district court to find against a party on an issue if the party "has been fully heard" on that issue and to enter a judgment against the party on any claim that can be maintained under the controlling law "only with a favorable finding on that issue." Fed. R. Civ. P. 52(c); *see Granite State Ins. Co. v. Smart Modular Techs., Inc.*, 76 F.3d 1023, 1031 (9th Cir. 1996) (finding that Rule 52(c) "authorizes the court to enter judgment at any time that it can appropriately make a dispositive finding of fact on the evidence") (citing Fed. R. Civ. P. 52(c) advisory committee's note). To support a judgment on partial findings under Rule 52(c), the court must "find the facts specially and state its conclusions of law separately" (pursuant to Rule 52(a)). Fed. R. Civ. P. 52(a), (c). "In deciding whether to enter judgment on partial findings under Rule 52(c), the district court is not required to draw any inferences in favor of the non-moving party; rather, the district court may make findings in accordance with its own view of the evidence." *Ritchie v. United States*, 451 F.3d 1019, 1023 (9th Cir. 2006).

> Equitable estoppel, which bars a patentee from receiving relief, consists of three elements: (i) the patentee must communicate to the accused infringer (by words, conduct or silence) that the patentee will not pursue an infringement claim; (ii) the accused infringer must rely on that communication; and (iii) the accused infringer must establish that it would be materially prejudiced if the patentee is now permitted to proceed with the infringement claim.

B. Braun Med., Inc. v. Abbott Labs., 124 F.3d 1419, 1425 (Fed. Cir. 1997); *see A.C. Aukerman Co. v. R.L. Chaides Const. Co.*, 960 F.2d 1020 (Fed. Cir. 1992). Silence alone will not create an estoppel unless there is a clear duty to speak or somehow the patentee's continued silence reinforces the defendant's belief that the defendant will be unmolested. *Id.* at 1043-44; *see also Hemstreet v. Computer Entry Sys. Corp.*, 972 F.2d 1290, 1295 (Fed. Cir. 1992) ("Mere silence must be accompanied by some other factor which indicates that the silence was sufficiently misleading as to amount to bad faith[.]"). Even if the three elements are met, the court must take into consideration all other evidence respecting the equities of the parties in exercising its discretion in deciding whether to allow the defense to bar the suit. *Id.* at 1043. *See Hynix*

Semiconductor Inc. v. Rambus Inc., 609 F. Supp. 2d 988, 1025 (N.D. Cal. 2009), *aff'd*, 645 F.3d 1336 (Fed. Cir. 2011).

Except where equitable estoppel is based solely upon intentional fraud, the burden of proof is the preponderance of evidence. "[W]hile the facts relied upon to establish equitable estoppel must be clear, positive, and unequivocal in their implication, these facts need not be established by any more than a fair preponderance of the evidence." *Aukerman Co.*, 960 F.2d at 1046.

A. Findings of fact (re: misleading conduct, reasonable reliance and material prejudice)

Ariosa and Illumina met in March 2011 and November 2011. The '794 patent issued June 2011. The SSA was executed January 2012. Ariosa purchased $14.4 million worth of Illumina equipment and reagents between 2012 and 2014. Ariosa published a study on its NIPT technology in April 2012. Illumina subsequently sued Arisoa.

Illumina asserts that it discovered the infringement in January 2014. Trial Tr. at 494:3-11. Mr. Naclerio is Illumina's former Head of Corporate Development. *Id*. at 394:15-16. Naclerio testified that Illumina contacted Ariosa within approximately a week from discovering the infringement. *Id*. at 456:18-20. ("And, in fact, as soon as we found out about that, within—within a week or so we did contact them and ask them about it."). Mr. Flatley is Illumina's executive chairman. *Id*. at 575:23. In January 2014, Flatley authorized the sending of a breach letter to Ariosa. *Id*. at 619:6-9. Flatley testified that Illumina and Ariosa communicated through letters and meetings between January 2014 and April 2014 concerning the infringement of the '794 patent. *Id*. at 620:12-621:12. Illumina filed a lawsuit against Ariosa in April 2014 alleging patent infringement. *Id*. at 504:6-11.

Naclerio testified that, before January 2014, he was not aware that Ariosa was infringing the '794 patent. *Id*. at 456:8-10 (Naclerio) ("So I certainly—I feel very strongly that my representation here was—was accurate that there's nothing that I'm aware of that they're infringing."). Flatley testified that, before January 2014, he was not aware that Ariosa was infringing the '794 patent. *Id*. at 604:17-19 (Flatley) ("**Q**. Was that something that you were aware of; that there might be an issue there? **A**. No, we were not aware of any issue."). Flatley

testified that Ariosa carried out a performance analysis and claimed it did not infringe on Illumina's intellectual property. *Id*. at 603:7-9. ("So when they told us they had done performance analysis, and didn't infringe this intellectual property, we assumed that they were correct about that.").

At trial, Flatley stated, "[a]nd if we're investing in a company, if there ever became an issue, we'd have the ability to license our technology to that company, and they would be close partners and collaborators with us. And so that's very low on the concern list at that point." *Id*. at 596:12-16. Naclerio testified, "You know, we were less concerned at this point about whether or not the ligation assay might -- might use our technology."). *Id*. at 431:23-25.

After the breach letter was sent in January 2014, Naclerio met with Dr. Song, an employee at Ariosa, at least twice regarding infringement. *Id*. at 496:2-19. At the second meeting between Dr. Song and Naclerio , Dr. Song stated, "[y]ou don't want to assert that patent against us." *Id*. at 496:10-11. Naclerio also testified the following:

> And then ultimately they told us that, you know, after—first they told us they don't infringe, and then told us there was something about the patent we didn't want to assert. Then when they finally said, oh, we already have a license, that's when we realized there's no way that they're being open with us, and that they're going to negotiate with us. Trial. Tr. at 566:9-14.

Ariosa challenged the '794 patent's validity. Dkt. No. 648. Ariosa expended a total of $40.2 million for research and development between 2011 and March 31, 2014. Dkt. No. 687-24 at 3.

B. Equitable estoppel analysis

1. Misleading conduct

Ariosa argues the trial evidence demonstrates that Illumina misled Ariosa into reasonably believing that Illumina would not sue under the '794 patent. Dkt. No. 650 at 5. Ariosa contends Illumina did nothing to communicate its intent to sue Ariosa for years after Illumina knew, or should have known, the details of the Harmony V1 assay through investment meetings between the companies' executives and Ariosa's scientific publication; invested in Ariosa; and continued to supply equipment and reagents to Ariosa under the SSA. *Id.* at 5-9. Thus, Ariosa argues

Illumina's "years of pre-suit conduct led to only one inference," that "it did not intend to sue Ariosa on the '794 patent." *Id.* at 9. Illumina responds it did not mislead Ariosa because the evidence shows that Illumina had no duty to inform Ariosa of the Harmony test's infringement of the '794 patent. Dkt. No. 671 at 5-6. Illumina argues that Ariosa never disclosed to Illumina sufficient details of the Harmony test or any of Ariosa's freedom to operate analysis, and the evidence shows Illumina "became aware of Ariosa's infringement of the '794 patent in January 2014," three months before Illumina filed suit. *Id.* at 6-13.

"The first element of equitable estoppel concerns the statements or conduct of the patentee which must 'communicate something in a misleading way.'" *Aukerman*, 960 F.2d at 1042. "The patentee's conduct must have supported an inference that the patentee did not intend to press an infringement claim against the alleged infringer." *Id.* "'Conduct' may include specific statements, action, inaction, or silence where there was an obligation to speak." *Id.* at 1028. The "plaintiff's inaction must be combined with other facts respecting the relationship or contacts between the parties to give rise to the necessary inference that the claim against the defendant is abandoned." *Id.* at 1042. Where equitable estoppel arises because an alleged infringer is misled by a patentee's silence, such silence alone "will not create an estoppel unless there was a clear duty to speak . . . or somehow the patentee's continued silence reenforces the defendant's inference from the plaintiff's known acquiescence that the defendant will be unmolested." *Id.* at 1043-44; *see Hemstreet v. Computer Entry Sys. Corp.*, 972 F.2d 1290, 1295 (Fed. Cir. 1992) (finding that the patentee's silence "must be accompanied by some other factor which indicates that the silence was sufficiently misleading as to amount to bad faith").

Ariosa claims that the present case is analogous to cases in which courts granted equitable estoppel. *See* Dkt. No. 686 at 6-8. Two of the cases that Ariosa cites to are readily distinguishable. First, *Aukerman* is distinguishable because the patentee in that case threatened to sue and then remained silent without action for eight years. *See Aukerman*, 960 F.2d at 1026-1027. In a similar manner, in *Aspex Eyewear Inc. v. Clariti Eyewear, Inc.*, the patentee also threatened suit and then remained silent for three years without action. 605 F.3d 1305, 1309 (Fed. Cir. 2010). By contrast, Illumina did not threaten suit and then remain silent for a long period of

time without action. In fact, Illumina testified that it found out about the infringement in January 2014 and then filed a lawsuit shortly after in April 2014. *See* Trial Tr. at 494:3-11, 504:6-11. Naclerio, Illumina's former Head of Corporate Development, further testified that Illumina contacted Ariosa within approximately a week from discovering the infringement. Trial Tr. at 394:15-16, 456:18-20 ("And, in fact, as soon as we found out about that, within -- within a week or so we did contact them and ask them about it."). Flatley, Illumina's executive chairman, also testified that Illumina and Ariosa corresponded through multiple letters and meetings concerning the infringement of the '794 patent between January 2014 and April 2014. *Id*. at 575:23, 620:12-621:12. Nevertheless, "that an immediate threat of enforcement followed by silence may be the most common scenario does not mean that it is the only set of facts which can support a finding of misleading silence." *ABB Robotics, Inc. v. GMFanuc Robotics Corp.*, 52 F.3d 1062, 1064 (Fed. Cir. 1995).

However, Ariosa does not find the support it seeks in *High Point SARL v. Sprint Nextel Corp.*, 817 F.3d 1325 (Fed. Cir. 2016), in which the court granted equitable estoppel and found there to be misleading conduct. In *High Point*, a plaintiff patentee's predecessors had a licensing agreement with the defendant Sprint, and "the licensing activity between Sprint and High Point's predecessors-in-interest covered the patents-in-suit." *High Point*, 817 F.3d at 1331. After obtaining the patents, High Point sued Sprint for "violating the licensing agreements and alleged that the Sprint CDMA network operated through the combination of licensed and unlicensed equipment to facilitate the transmission of voice call traffic in an infringing manner." *Id*. at 1328. In *High Point*, there was no dispute that the license from the patentee's predecessors-in-interest "covered the patents-in-suit." *Id*. at 1330. Additionally, there was evidence that the predecessors-in-interest "were aware of Sprint's intent to create CDMA infrastructure with equipment supplied from various vendors," and the patentee did not sue until 2008, approximately seven years after the alleged infringer's activity "fell outside the licenses." *Id*. at 1328, 1330-31.

Unlike the patentee in *High Point*, which explicitly licensed activity related to the patents-in-suit, Illumina did not license the '794 patent to Ariosa. *See* Dkt. No. 633 at 2. Furthermore, unlike in *High Point* where the patentee was clearly aware of the infringing activity, there is

conflicting evidence as to whether Illumina was aware of the infringing activity before January 2014.

Naclerio and Flatley testified that they did not believe the activity was infringing. Trial Tr. at 604:17-19 (Flatley) (**Q**. "Was that something that you were aware of; that there might be an issue there?" **A**. "No, we were not aware of any issue."); Trial Tr. at 456:8-10 (Naclerio) ("So I certainly—I feel very strongly that my representation here was -- was accurate that there's nothing that I'm aware of that they're infringing."). Additionally, Flatley testified that Ariosa had carried out a performance analysis and claimed that it did not infringe on Illumina's intellectual property. *Id*. at 603:7-9 ("So when they told us they had done performance analysis, and didn't infringe this intellectual property, we assumed that they were correct about that."). Finally, contrasted to the patentee in *High Point,* which waited at least seven years to sue, Illumina filed a lawsuit in April 2014 after finding out about the infringement in January 2014. *See id*. at 494:3-11, 504:6-11.

Although Flatley and Naclerio testified that Illumina's primary concern was not whether Ariosa infringed on the '794 patent, this does not amount to an admission that Illumina was aware of the infringement. Trial Tr. at 431:23-25 (Naclerio) ("You know, we were less concerned at this point about whether or not the ligation assay might -- might use our technology."); *Id*. at 596:12-16 ("And if we're investing in a company, if there ever became an issue, we'd have the ability to license our technology to that company, and they would be close partners and collaborators with us. And so that's very low on the concern list at that point."). In conclusion, based on the specific circumstances in the present case, the Court finds that Illumina did not engage in misleading conduct.

2. Reasonable reliance

Although the Court does not find that there was misleading conduct, it will now consider the second element of reliance. Ariosa contends the evidence at trial shows that Ariosa invested heavily in developing and commercializing the Harmony V1 assay because Ariosa took Illumina's conduct as tacit approval of Ariosa's Freedom to Operate analysis, and because the SSA assured Ariosa that it had access to a supply of equipment and reagents. Dkt. No. 650 at 9:26-11:13.

Ariosa argues that it took "proper precautions" for investing resources to develop the Harmony test. *Id.* at 10. Ariosa argues that it regarded the SSA as ensuring access to needed supplies and thus the SSA "played a key role in Ariosa's sense of security in commercializing Harmony." *Id.* Illumina responds that the evidence shows Ariosa did not reasonably rely on Illumina because it was Ariosa's obligation under the SSA to "ensure it had the rights from Illumina" to perform the Harmony test, and because Ariosa acted under its own business judgment to develop and commercialize the Harmony test. Dkt. No. 671 at 14.

To establish reliance, the defendant "must show that, in fact, it substantially relied on the misleading conduct of the patentee in connection with taking some action." *Aukerman*, 960 F.2d at 1042-43. "To show reliance, the infringer must have had a relationship or communication with the plaintiff which lulls the infringer into a sense of security in going ahead with" investing in the accused activity. *Id.* at 1043. A defendant "need not prove precisely what alternative paths it would have taken, or that every marketing decision was based on reliance" on a patentee's silence. *Enel Co., LLC v. Schaefer*, No. 12-CV-1369-IEG WMC, 2013 WL 5727421, at *11 (S.D. Cal. Oct. 22, 2013) (citing *Aspex Eyewear*, 605 F.3d at 1312).

The Federal Circuit has stated that the second element is not satisfied when "there is a total absence in the record of any showing by [the alleged infringer] that its activities were in reliance upon supposed actions of [the patentee], rather than a *business judgment* of its own—a judgment which subsequent events may well prove to have been faulty." *Hemstreet v. Computer Entry Sys. Corp.*, 972 F.2d 1290, 1294-95 (Fed. Cir. 1992) (emphasis added). The Federal Circuit reiterated this point in *Gasser Chair Co. v. Infanti Chair Mfg. Corp.*, 60 F.3d 770 (Fed. Cir. 1995), *vacated on other grounds*, 95 F.3d 1165 (1996) (unpublished opinion). In *Gasser*, the patentee (Gasser) sent multiple letters to Infanti accusing it of patent infringement. *Id.* at 772. Because Infanti refused to completely cease the allegedly infringing operations, Gasser sued Infanti for infringement. *Id.* The Federal Circuit rejected Infanti's request for equitable estoppel and stated the following: "Infanti ignored Gasser's charges of infringement because he believed the patent was invalid. Thus, Infanti totally failed to show that he acted in reliance on supposed actions of Gasser rather than a *business judgment*." *Gasser*, 60 F.3d at 776 (Fed. Cir. 1995) (emphasis

added) (citing *Hemstreet*, 972 F.2d at 1294–95; and then citing *Vaupel Textilmaschinen KG v. Meccanica Euro Italia SPA*, 944 F.2d 870, 879 (Fed. Cir. 1991)). Therefore, believing that the relevant patent is invalid supports that the alleged infringer did not rely on misleading conduct but rather relied on its own business judgment. As a result, when an alleged infringer carries out an action based on a business judgment, the action is not done in reliance on misleading conduct.

In the present case, when Naclerio, on behalf of Illumina, met with Ariosa regarding infringement, Ariosa's Dr. Song stated that "[y]ou don't want to assert that patent against us." Trial Tr. at 496:10-11. Naclerio also testified that the following occurred:

> And then ultimately they told us that, you know, after—first they told us they don't infringe, and then told us there was something about the patent we didn't want to assert. Then when they finally said, oh, we already have a license, that's when we realized there's no way that they're being open with us, and that they're going to negotiate with us.

Trial. Tr. at 566:9-14. In addition, like the patentee in *Gasser* who believed the patent was invalid, Ariosa believed the '794 patent was invalid and thus challenged the patent's validity. *See* Dkt. No. 648. That Ariosa repeatedly tried to justify its actions, coupled with Ariosa's accusations of invalidity despite Illumina's letter of infringement, shows that Ariosa relied on its own business judgment and "did not establish that [it] would have acted differently under other circumstances." *See Gasser*, 60 F.3d at 776.

Once again, even if the above precedent did not favor Illumina, because the Court holds that Illumina did not engage in misleading conduct, the element of reasonable reliance on misleading conduct cannot be satisfied.

3. Material prejudice

Ariosa argues the trial evidence shows that Ariosa's $14.4 million investment to purchase Illumina equipment and reagents to develop and commercialize the Harmony test "flowed from Illumina's conduct conveying assurances that it would not sue," and therefore was a change in economic position sufficient to constitute material prejudice. Dkt. No. 650. Ariosa argues that it was prejudiced by Illumina's conduct because "Ariosa could have designed its Harmony test" and

adopted the assay format used in Harmony V2, in the event this Court finds that Harmony V2 does not infringe the '794 patent. *Id.* at 12. Illumina responds that the evidence shows Ariosa did not suffer material prejudice because Ariosa actually "benefitted from its investment" through its use of the purchased reagents and sequencing equipment, "enjoyed everything it bought, reaped profits from selling its test, and fully recouped its monetary investment." Dkt. No. 671 at 16. Illumina avers that Ariosa could not have designed around the '794 patent because the jury found Harmony V2 infringed the patent. *Id.*

The third element of equitable estoppel is the following: "*due to its reliance*, the alleged infringer will be materially prejudiced if the patentee is allowed to proceed with its claim." *Ecolab, Inc. v. Envirochem, Inc.*, 264 F.3d 1358, 1371 (Fed. Cir. 2001) (emphasis added) (citing *Scholle Corp. v. Blackhawk Molding Co., Inc.*, 133 F.3d 1469, 1473 (Fed. Cir. 1998)). Material prejudice "may be a change of economic position or loss of evidence." *Aukerman*, 960 F.2d at 1043; *see Aspex*, 605 F.3d at 1305 ("Prejudice may be shown by a change of economic position flowing from actions taken or not taken by the patentee.").

In *Aspex Eyewear*, the court stated the following in concluding that there was no material prejudice:

> Marketing products, which is all [the alleged infringer] did here, generally does not require the same kind of investment as developing and manufacturing products. . . . In this case, the record leaves many questions about economic prejudice because [the alleged infringer] did not manufacture any products but simply marketed them.

Aspex Eyewear, 605 F.3d at 1318-19. Unlike the alleged infringer in *Aspex* who only marketed and did not develop and manufacture products, Ariosa spent millions on developing the Harmony Test. Specifically, Ariosa expended $40.2 million for research and development between 2011 and March 31, 2014. *See* Dkt. No. 687-24 at 3. Ariosa's activities and expenditures were certainly material; however, since the Court has found neither misleading conduct nor reliance, it finds no material prejudice resulting therefrom.

4. Other equitable factors

Illumina argues the jury's factual findings preclude Ariosa's equitable estoppel defense.

Dkt. No. 671 at 2-5. Illumina contends that the jury's verdict implicitly supports a finding that Illumina acted in good faith in filing this lawsuit. *Id.* at 3. Illumina argues that the trial evidence shows Ariosa threatened Illumina about asserting the '794 patent and made "bad faith" attempts to invalidate the patent by unsuccessfully challenging the patent's inventorship and ownership. *Id.* at 4-5. Illumina argues the trial evidence shows that the balance of equities weighs against finding equitable estoppel as a matter of law. *Id.* at 5.

Ariosa responds that the intent behind Illumina's misleading conduct is irrelevant, arguing that a court can find estoppel even when the estopped party did not intend to mislead the other party. Dkt. No. 686 at 3. Ariosa furthers contends that although it informed Illumina of its view of noninfringement, Illumina chose to remain silent despite having the opportunity to ask questions. Finally, Ariosa argues that the jury did not find in the verdict that Ariosa acted willfully regarding infringement.

"[T]he trial court must, even where the three elements of equitable estoppel are established, take into consideration any other evidence and facts respecting the equities of the parties in exercising its discretion and deciding whether to allow the defense of equitable estoppel to bar the suit." *Aukerman*, 960 F.2d at 1043.

Since the Court finds that the three elements of equitable estoppel are not satisfied and rules in favor of Illumina, the Court declines to consider the rest of Illumina's contentions.

IV. Plaintiffs' motion for a finding that assignor estoppel bars Ariosa from challenging the validity of the '794 patent (Rule 52(a)) (Dkt. No. 661)

On March 16, 2018, Illumina filed a motion for a finding, pursuant to Rule 52(a), that assignor estoppel bars Ariosa from challenging the validity of the '794 patent. Upon considering the parties' papers and the evidence in the record, the Court makes the following finding of facts and conclusions of law.

A. Findings of Fact

The Court's Findings of Fact are based on the Court's independent review of the evidence presented in the case-in-chief.

---Assignment of the patent application giving rise to the '794 patent.

1. Drs. Stuelpnagel and Oliphant assigned the rights to their invention in the '727 application to Verinata.

2. The assignment stated the following:

Assignors sell, assign, and transfer to Assignee, the entire right, title, and interest in and to said invention, said application, any applications entitled to benefit of priority to said application under Title 35, United States Code, Sections 120, 121 or 251, which include divisionals, continuations and reissues, and any Letters Patent that may be granted on said invention or these applications in the United States and throughout the world. Dkt. No. 396-2 at 2.

3. The '727 application, after modifications and changes, eventually led to the '794 patent. *See* Trial Tr. at 1050:11-14 (Dkt. No. 603).

---Privity between Ariosa and Drs. Oliphant and Stuelpnagel

1. Dr. Stuelpnagel was the founder and Executive Chairman of Ariosa. *See* Trial Tr. (1/11/2018) at 741:10-18.

2. Dr. Stuelpnagel provided legal advice regarding the Harmony Test. *Id.*. (1/11/2018) at 702:25-703:6.

3. Dr. Oliphant was the Chief Science Officer of Ariosa and was responsible for the development of the Harmony V2 Test. *See* Trial Tr. (1/16/2018) at 1062:14-19.

---Drs. Oliphant and Stuelpnagel's inventorship

1. The '794 patent lists Drs. Stuelpnagel and Oliphant as inventors. *See* Trial Tr. at 706:22-25, 1049:15-18.

2. Drs. Stuelpnagel and Oliphant both signed oaths of inventorship for the '727 application. *See* Trial Tr. at 731:10-12, 1049:19-23.

B. Conclusions of law

"Assignor estoppel is an equitable doctrine that prevents one who has assigned the rights to a patent (or patent application) from later contending that what was assigned is a nullity. The

estoppel also operates to bar other parties in privity with the assignor, such as a corporation founded by the assignor." *Diamond Sci. Co. v. Ambico, Inc.*, 848 F.2d 1220, 1224 (Fed. Cir. 1988). "If [a challenged] patent claims an invention within the assignment agreement, the assignor estoppel doctrine operates to prevent [the assignor] from contesting the validity of the patent." *Q.G. Prod., Inc. v. Shorty, Inc.*, 992 F.2d 1211, 1213 (Fed. Cir. 1993); *see Diamond*, 848 F.2d at 1224 (finding that allowing an assignor to make an "implicit representation . . . that the patent rights that he is assigning . . . are not worthless . . . at the time of the assignment (to his advantage) and later to repudiate it (again to his advantage) could work an injustice against the assignee").

"This doctrine prevents the 'unfairness and injustice' of permitting a party 'to sell something and later to assert that what was sold is worthless.'" *Mentor Graphics Corp. v. Quickturn Design Sys., Inc.*, 150 F.3d 1374, 1377 (Fed. Cir. 1998) (citing *Diamond*, 848 F.2d at 1224). "A determination whether assignor estoppel applies in a particular case requires a balancing of the equities between the parties." *Carroll Touch, Inc. v. Electro Mech. Sys., Inc.*, 15 F.3d 1573, 1579 (Fed. Cir. 1993). "That determination is a matter committed to the sound discretion of the trial court." *Id.*

1. Timing

Defendant argues that the Court should deny Illumina's motion because it was filed "later than 28 days after the entry of judgment." Dkt. No. 661 at 2 (citing Fed. R. Civ. P. 52(b)). Plaintiffs respond that "there has not yet been a valid entry of judgment because the Court has not yet ruled on Ariosa's equitable estoppel defense--or resolved the inventorship issue." Dkt. No. 694 at 2. In the unique posture of this case, the Court agrees with plaintiffs, and will consider the motion timely.

2. Privity

Plaintiffs argue that Ariosa is barred from challenging the validity of the '794 patent because Drs. Stuelpnagel and Oliphant were inventors of the '794 patent, who assigned all their

rights to the patent to plaintiffs, and Ariosa is in privity with Drs. Stuelpnagel and Oliphant. Dkt. No. 661 at 2. Plaintiffs point to Dr. Stuelpnagel's testimony at trial demonstrating he was founder and Executive Chairman of Ariosa, which "availed itself of his knowledge in evaluating whether Harmony infringed the '794 patent," and "corroborating Dr. Oliphant's role as Chief Scientific Officer in the development of the Harmony test and the infringing DANSR array." *Id.* at 4-5.

Assignor estoppel prevents "those in privity with the assignor from contending that the patent is a nullity." *Shamrock Techs., Inc. v. Med. Sterilization, Inc.*, 903 F.2d 789, 793 (Fed. Cir. 1990). The issue is whether Ariosa and Drs. Stuelpnagel and Oliphant are in privity, such that assignor estoppel would preclude Ariosa from challenging the validity of the ''794 patent. Concerning privity, the Federal Circuit wrote the following:

> If an inventor assigns his invention to his employer company A and leaves to join company B, whether company B is in privity and thus bound by the doctrine will depend on the equities dictated by the relationship between the inventor and company B in light of the act of infringement. The closer that relationship, the more the equities will favor applying the doctrine to company B.

Shamrock Techs., 903 F.2d at 793.

The Court finds there is privity between Ariosa and both Drs. Stuelpnagel (founder and Executive Chairman at Ariosa) and Oliphant (Chief Scientific Officer who worked on the Harmony V2 Test). Trial Tr. at 741:10-18, 796:18-22, 1062:14-19. Notably, Ariosa does not dispute privity. Dkt. No. 486.

3. Inventorship

Plaintiffs argue that Drs. Stuelpnagel and Oliphant assigned their undivided interest in the '794 patent to Illumina when they assigned their interest in the "entire invention" disclosed in the '727 application, which later issued as the '794 patent. Dkt. No. 661 at 5-6. Plaintiffs contend that defendant did not present clear and convincing evidence to negate Drs. Stuelpnagel's and Oliphant's presumptive inventorship because they admitted at trial that they contributed to the '794 patent a "singular idea" that is claimed in the patent; trial evidence showed that the '794 patent claims encompass their "singular idea" even when it is defined narrowly; they admitted at trial to inventing Illumina's Golden Gate product, which the trial evidence showed is covered by

the ’794 patent; and the trial evidence showed that Dr. Stuelpnagel never denied his inventorship before this lawsuit was filed. *Id.* at 7-16.

Defendant argues that Drs. Stuelpnagel and Oliphant (and therefore Ariosa) are not estopped from challenging the validity of the ’794 patent because the invention they assigned is outside the claims of the ’794 patent. Dkt. No. 683 at 4. Ariosa argues the doctors’ singular idea of extension and ligation was embodied in Claim 5, which was removed from the final ’794 patent, thus proving the ’794 patent does not encompass the doctors’ invention. *Id*. at 11. Illumina contends that the ’794 patent still encompasses the assigned invention because the term “substantial complementarity” includes “perfect complementarity,” and the allele-specific extension and ligation requirement is fulfilled by claims 2, 13, 19, and 20; for example, it is fulfilled by claim 13 because SNPs are detected and is fulfilled by claim 19 because it adds extension and ligation. Dkt. No. 661 at 10-11. Ariosa responds that the doctors’ invention regarding extension and ligation was not embodied in the ’794 patent. First, Ariosa argues the “perfect complementarity” requirement is missing because substantial complementarity differs from perfect complementarity. Dkt. No. 683 at 14-17. Second, Ariosa contends the allele-specificity aspect is not fulfilled because the perfect complementarity requirement only pertains to “the approximately *four terminal bases of the interrogation position*,” meaning that being able “to detect SNPs is irrelevant.” *Id*. at 17 (emphasis in original).

In response to Illumina’s argument regarding the Golden Gate assay, Ariosa contends that “[n]owhere does Dr. Cooper address whether the Golden Gate assay employs perfect complementarity at the several terminal bases of an interrogation position as Dr[s]. Stuelpnagel and Oliphant conceived.” *Id*. at 18 (citations omitted). Moreover, Ariosa argues that the prosecution history of the ’727 patent shows that the doctors’ invention was removed from the final version of the’794 patent. *Id*. at 19-20.

Alternatively, Ariosa argues that, even if claims 19 and 20 embody the assigned invention, those claims are not the subject of the litigation. *Id*. at 21. Thus, Ariosa contends assignor estoppel should still not preclude Ariosa from challenging the validity of the patent.

The Federal Circuit has not required that the language of the original application track exactly the language of the patent claims in order for assignor estoppel to apply. *See Diamond*, 848 F.2d at 1226. *Diamond*, like the present case, involved assigned applications that later became patents. *Id*. In *Diamond*, the Federal Circuit found the following: "[t]hat Diamond may have later amended the claims in the application process (a very common occurrence in patent prosecutions), with or without Dr. Welter's assistance, does not give appellants' arguments against estoppel any greater force." *Id*. In fact, the Federal Circuit pointed out that "Dr. Welter assigned the *rights* to his invention, irrespective of the particular language in the claims describing the inventions when the patents were ultimately granted." *Id*.

The Federal Circuit in *Diamond* did outline the following exception to assignor estoppel:

> To the extent that Diamond may have broadened the claims in the patent applications (after the assignments) beyond what could be validly claimed in light of the prior art, *Westinghouse* may allow appellants to introduce evidence of prior art to narrow the scope of the claims of the patents, which may bring their accused devices outside the scope of the claims of the patents in suit.

Id. (citing *Westinghouse Elec. & Mfg. Co. v. Formica Insulation Co.*, 266 U.S. 342, 350 (1924)). This narrowing of the scope of the claims is not equivalent to challenging a patent's validity, as narrowing the scope is only a defense against "infringement claims" and does not allow the company in privity with the assignor to engage in "raising invalidity defenses." *Id*. This implies that patent invalidity cannot be used as a challenge even when dealing with claims that are broadened after the assignment of a patent application. *Id*. at 1226. As a result, the Federal Court strongly cautions courts from unduly restricting or limiting assignor estoppel.

Brocade Commc'ns Sys., Inc. v. A10 Networks, Inc., No. 10-CV-03428-LHK, 2012 WL 2326064, at *3 (N.D. Cal. June 18, 2012), extended the *Diamond* caution even further. The court in *Brocade* held that "an inventor who assigns rights to all his inventions prior to the filing of a patent application on any particular invention is estopped from challenging validity of any issued patents." *Id*. The court rejected the argument that assigning the rights before the patent application precluded assignor estoppel supposedly because the joint inventors could not have "vouched that the assigned patent rights had any value." *Id*. *Brocade*, in conjunction with

Diamond, advises this Court that assignors of patent applications, despite modifications to the patent application later, should be subject to assignor estoppel.

The breadth of the assignment language in this case is also significant. In *BASF Corp. v. Aristo, Inc.*, 872 F. Supp. 2d 758, 775 (N.D. Ind. 2012), *reconsidered on other grounds*, No. 2:07 CV 222 PPS, 2012 WL 2420999 (N.D. Ind. June 26, 2012), a joint inventor assigned the rights to a patent application and the invention. *Id*. The inventor argued that assignor estoppel could not bar his assertions of patent invalidity because the claims he assigned in the application were different from the claims in the final patent; specifically, the "patent application claims changed during prosecution without his approval." *Id*. Nevertheless, the district court held that the inventor was barred by assignor estoppel because of the language in his assignment, which stated that "the entire right, title and interest in, to and under the said invention, and the said application and all divisions, renewals, and continuations thereof, and all Letters of Patent of the United States which may be granted thereon and all reissues and extensions thereof." *Id*. The court held that the inventor was estopped because of the "breadth of this assignment" that was manifested in the wording of "said application and all divisions, renewals, and continuations thereof." *Id*.

Similar to the *BASF* assignor who asserted that the claims that were assigned differed from the claims in the final patent, Ariosa argues that assignor estoppel cannot apply to Ariosa because the claims in the '727 application were different from the claims in the final '794 patent. Dkt. No. 683. The language of Drs. Stuelpnagel and Oliphant's assignment is almost the same as the language of the assignment in *BASF*. Drs. Stuelpnagel and Oliphant's assignment states that "the entire right, title, and interest in and to said invention, *said application, any applications . . . which include divisionals, continuations, and reissues*, and any Letters Patent that may be granted on said inventions or these applications . . . ." Dkt. No. 396-2 at 2 (emphasis added). Just as the inventor in *BASF* assigned "what ultimately became the # 210 Patent," the doctors likewise assigned to Verinata what ultimately became the '794 patent. Hence, Ariosa, which is in privity with Drs. Stuelpnagel and Oliphant, is estopped from challenging the validity of the '794 patent, notwithstanding the numerous arguments that Ariosa asserts regarding the differences between the '794 patent claims and the '727 application claims.

Ariosa argues that *Leading Edge Tech. Corp. v. Sun Automation, Inc.*, Civ. S. No. H-90-2316, 1991 U.S. Dist. LEXIS 20766 (D. Md. Sep. 24, 1991) suggests that the Court should not apply assignor estoppel. Dkt. No. 683 at 3. In *Leading Edge*, the court refused to grant summary judgment regarding assignor estoppel based on its inability to answer as a matter of law whether "the assigned invention is identical to the invention or inventions claimed in the patents in suit." *Leading Edge*, 1991 U.S. Dist. LEXIS 20766, at *8. This inquiry was necessary solely because the assignment did not explicitly assign continuations, divisionals, or reissues; the assignment only explicitly assigned "the full and exclusive right ... in and to the said invention, as described in the application filed April 28, 1980 . . . ." *See id*. at 2; Ex. A [Order No. 15, *In the Matter of Certain Microfluidic Devices* (Inv. No. 337-TA-1068)(Apr. 20, 2018)] at 13 (Dkt. No. 696). By contrast, as discussed above, Drs. Stuelpnagel and Oliphant's assignment was much broader than the assignment in *Leading Edge*.

In sum, this Court finds that Ariosa is estopped from challenging the validity of the '794 patent.

V. Plaintiffs' motion for permanent injunction (Dkt. Nos. 660, 666)

Illumina moves to enjoin defendants Ariosa Diagnostics, Inc./Roche Molecular Systems, Inc. from making, selling, offering to sell, using, and importing the Harmony™ test in the United States.

A patent grants to the patentee "the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States." 35 U.S.C. § 154. Section 283 of the Patent Act allows a court to "grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent." 35 U.S.C. § 283. To obtain a permanent injunction, a plaintiff must show that (1) "it has suffered an irreparable injury"; (2) "remedies available at law, such as monetary damages, are inadequate to compensate for that injury"; (3) "considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted"; and (4) "the public interest would not be disserved by a permanent injunction." *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391

(2006).

A. Irreparable injury

A patentee satisfies the irreparable injury prong by establishing that 1) "absent an injunction, it will suffer irreparable harm"; and 2) "a sufficiently strong causal nexus relates the alleged harm to the alleged infringement." *Apple Inc. v. Samsung Elecs. Co.*, 695 F.3d 1370, 1374 (Fed. Cir. 2012); *Apple Inc. v. Samsung Elecs. Co.*, 809 F.3d 633, 639 (Fed. Cir. 2015) (clarifying that the "causal nexus" requirement is met when there is "proof that the infringement causes the harm").

1. Direct competition

Plaintiffs argue they are in direct competition with, and accordingly irreparably harmed by, Roche's use of the DANSR technology. According to plaintiffs, the existence of two competing platforms means that every sale defendant makes is a sale Illumina loses. *See* Dkt. No. 666 at 8.

Plaintiffs argue that because Roche does not pay for the intellectual property it uses, Roche can undercut the price for NIPT tests and disrupt the market, causing plaintiffs to lose sales. Plaintiffs argue that "[o]nce a laboratory adopts a technology to develop its own NIPT test and that test is verified, it can be difficult to switch technologies." Dkt. No. 659 at 8. As a result, the long term losses are difficult to quantify. *Id*.

In addition, plaintiffs argue NIPT technology is an emerging market, and as a result Roche's direct competition with Illumina causes lost business opportunities, customers, and sales at a particularly crucial inflection point. *Id*. at 6, 8. Plaintiff contends that such losses tarnish Illumina's brand as "the most efficacious test, emasculates the exclusivity that is the promise of the patent grant, and frustrates the quantification of losses." *Id*. at 3.

Defendant responds that the focus of the competition should be between Ariosa and Illumina, not Roche and Illumina. Dkt. No. 682 at 7. Ariosa argues that by Illumina's own admission, Illumina is not a direct competitor with Ariosa. Dkt. No. 684-2 at 14 ("Illumina eliminated its IPT sales force and exited the market in which Ariosa operates.").

Defendant also argues that the Harmony test does not focus on the same market of in-house clinical laboratories that Illumina targets and that the presence of other third-party competitors suggests there is no irreparable harm. *Id*. at 7-8, 12. Defendant contends that Illumina conflates itself with these third-party licensees, and that competition between Ariosa and third-parties cannot fulfill the requirement of irreparable harm *because* the test requires a showing that the patentee itself, not a third party, has suffered irreparable harm. *Id*. at 8.

Defendant also attacks plaintiffs' reliance on Illumina executive Jeffrey Eidel's declaration, arguing that the declaration relies on multiple levels of hearsay. Furthermore, Ariosa disputes plaintiffs' contention that Roche's sales are expanding, emerging, or increasing. *Id*. at 10-11. According to defendant, Ariosa's Harmony sales have declined each year since the Roche acquisition. *Id*. at 11.

The Federal Circuit has held that "[d]irect competition in the same market is certainly one factor suggesting strongly the potential for irreparable harm without enforcement of the right to exclude." *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 702 F.3d 1351, 1363 (Fed. Cir. 2012) (citing *Broadcom Corp. v. Qualcomm Inc.*, 543 F.3d 683, 703 (Fed.Cir.2008)). Illumina claims Roche is a competitor because the Harmony test's DANSR platform embodies the '794 patent and directly competes with Illumina's technology platform for NIPT tests. Dkt. No. 695 at 2. "Neither DANSR nor the '794 Patent are themselves NIPT tests—they are the technology platform on which the test is performed." Dkt. No. 695 at 3. Illumina argues its platform enables licensing and, for instance, test centers, to adopt tests that are far more valuable than the individual tests themselves. *See* Dkt. No. 666 at 4 (citing Trial Tr. at 1111:8-13).

Illumina licenses its NIPT pool of patents along with its products from the Sale and Supply Agreement. Trial Tr. 1109: 9-15. The license allows clinical laboratories to "[b]ring in-house their own tests." Dkt. No. 666 at 6. Unlike Illumina, Ariosa does not utilize a licensing model; instead, Ariosa sells the Harmony V2 test directly. As a result, the Court finds that Ariosa is not in direct competition with plaintiffs. Rather, defendant competes with Illumina's licensees, not with Illumina. In *ActiveVideo Networks, Inc. v. Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1338 (Fed. Cir. 2012), ActiveVideo licensed its "Cloud TV" platform to Cablevision. ActiveVideo

moved for a permanent injunction against Verizon, which was using technology that infringed on ActiveVideo's patent, because Cablevision could lose subscribers to Verizon. *Id.* When Cablevision lost subscribers to Verizon, ActiveVideo would lose a fee because Cablevision paid ActiveVideo a licensing fee for every subscriber it had. *Id.* The Federal Circuit explained there was no "direct competition" because "ActiveVideo does not lose market share when Cablevision loses a subscriber to Verizon, it loses the Cablevision licensing fee. Cablevision, not ActiveVideo, has lost market share." *Id.* The Court then concluded that "such a loss is certainly not irreparable. Straight-forward monetary harm of this type is not irreparable harm." *Id.* The Federal Circuit also clarified that "[t]he harm to ActiveVideo due to Verizon's infringement is readily quantifiable. When Verizon pays ActiveVideo a per month royalty for each FiOS–TV subscriber, then ActiveVideo is adequately compensated." *Id.*

As in *ActiveVideo*, where ActiveVideo licensed its patent to Cablevision, Illumina licenses its NIPT patent pool to various licensees. Additionally, as in *ActiveVideo*, where the plaintiff received a licensing fee per subscriber, here Illumina receives payment from every company that obtains a license to its patent pool. In the same way that Verizon's use of infringing technology to obtain a subscriber would cause quantifiable harm to ActiveVideo, Ariosa's use of Harmony V2 causes quantifiable harm to Illumina by taking away a potential licensee. Similarly, this quantifiable harm to Illumina is not irreparable and there is no direct competition between Illumina and Ariosa. Rather, the Court finds that only third party licensees directly compete with Ariosa.

Both parties contest whether AcfS, a product provided by Ariosa, should also fall under the permanent injunction. *See* Dkt. No. 697-4 at 1; Dkt. No. 684-2 at 7. Given that the Court finds no direct competition between plaintiffs and defendant, the Court finds that the production of AcfS should not be enjoined. If Harmony V2 is not in direct competition, AcfS cannot be in direct competition.

2. Adequacy of legal remedies

Plaintiffs argue that monetary damages are inadequate to compensate them because

plaintiffs are forced to compete with a multi-national conglomerate and because the injury to Illumina's reputation is not compensable with monetary damages. Dkt. No. 666 at 9-11. Illumina argues that because the patent has not been licensed and has been kept for exclusive use by Illumina, as it is not part of the NIPT patent pool, the company is irreparably damaged by defendant's Harmony tests. *Id.* Illumina states that "Illumina has not and does not have interest in licensing its patents such as the '794 Patent to suppliers of competing platforms such as Roche." Dkt. No. 659-4 at 15.

Defendant claims that plaintiffs' licensing model shows money damages are adequate. First, Illumina participated in the NIPT market as a licensor. Dkt. No. 682 at 5. Defendant argues that, per plaintiffs' own words, Illumina's business goal remains "to license everyone." Dkt. No. 684-2 at 8. Defendant argues that the trial transcript suggests that Illumina intended to license to as many NIPT companies as possible. Dkt. No. 682 at 5.

Second, defendant points out that Illumina not only represented it was willing to license the '794 patent to Ariosa, but suggested its very purpose in bringing this lawsuit was to get Ariosa to take a license. *Id*. at 5-6. Defendant argues that Illumina is not seeking to reserve the '794 patent for its own exclusive use, as it does not use the '794 for either NIPT technology or any other purpose. *Id*. at 5. According to defendant, the '794's primary use was in GoldenGate, which was discontinued in December of 2015. *Id*.

This Court is unconvinced by Illumina's argument that the harm resulting from competing against Roche is not compensable by monetary damages. The Court finds that, as the Federal Circuit explained in *ActiveVideo*, in cases such as this one where the licensees compete with the infringer, royalties are adequate forms of compensation. *See ActiveVideo*, 694 F.3d at 1338.

In addition, the Federal Circuit ruled on injuries to reputation in *Douglass Dynamics, LLC v. Buyers Products Co.*, 717 F.3d 1336, 1345 (Fed. Cir. 2013). In *Douglass*, the patentee never licensed and intentionally chose not to license the infringed patents in order to retain market exclusivity. *Id*. The Federal Circuit ruled that exclusivity "is an intangible asset that is part of a company's reputation," and then proceeded to hold that remedies at law were "inadequate to compensate Douglass for at least the reputation loss Douglass has suffered from Buyer's

infringement." *Id.* Thus a company which deliberately does not license an infringed patent has suffered irreparable harm and cannot be adequately compensated by legal remedies.

As both parties contest whether Illumina intended to license the '794 patent, the Court will focus on the issue of whether Illumina deliberately did not license out its patent to retain market exclusivity. Accordingly, the main inquiry is whether there was an intention to keep the '794 patent, not the NIPT pool, exclusive. During trial, Illumina explicitly attributed the instant litigation to the fact that Roche "won't take a license to the intellectual property of Illumina, and pay for the intellectual property it uses." Trial Tr. 128:5-13. In addition, one of the main contentions at trial was whether Ariosa actually had a license to the '794 patent. *See* Trial Tr. 139:25-140:1. Based on the record before the Court, it is clear that Illumina intended to license the '794 patent to Ariosa; and, given that Illumina did not have an intention to retain market exclusivity, this Court holds Illumina's argument regarding exclusivity fails.

3. Balance of hardships

Plaintiffs argue the balance of hardships between plaintiffs and defendant supports an injunction. *See* Dkt. No. 666 at 11. Plaintiffs note that Roche bought Ariosa with its "eyes wide open about the litigation," meaning that, having been forewarned of the instant dispute, Roche is precluded from arguing about the resulting hardship of a permanent injunction. *Id.* Defendant argues that the strong possibility of success on an appeal weighs in favor of showing that the balance of hardships should not lead to an injunction. Dkt. No. 682 at 18. Defendant also argues that there will be adverse consequences to Ariosa's business, having invested millions of dollars in the Harmony Test over a period of eight years. *Id.* at 18-19. Defendant also contends that Illumina will receive its desired royalty payments, and the status-quo of the last six years will remain intact. *Id* at 19.

To determine the balance of hardships, the Court must determine whether Ariosa or Roche is the relevant party. Roche Molecular Systems Inc. bought Ariosa around December 2014. Dkt. No. 517 at 8 n.8. Roche was named a party during the course of this action, but was dismissed pursuant to stipulation and subsequently deemed a party to any judgment. Dkt. No. 375 at 2. As a

result, the focus of the trial was on Ariosa. In addition, the jury verdict refers only to Ariosa and does not mention Roche. *See* Dkt. No. 633. Since the jury considered Ariosa as the relevant party, this Court concludes that Ariosa is the relevant party.

In *Hynix Semiconductor Inc. v. Rambus Inc.*, 609 F. Supp. 2d 951, 984 (N.D. Cal. 2009), the district found that "decimat[ing]" an infringer's business tips the balance in the favor of the infringer. The court acknowledged the Federal Circuit's ruling that "[o]ne who *elects* to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected." *Id.* (quoting *Windsurfing Int'l Inc. v. AMF, Inc.*, 782 F.2d 995, 1003 (Fed. Cir. 1986)). However, the district court considered that to have changed the technology of the potentially infringing product could cost huge sums of money just "to avoid infringement of claims that had not yet been adjudicated valid and enforceable." *Id.* at 985. That, coupled with the "immediate and devastating harm that an injunction would deal," tipped the balance in favor of the non-moving party. *Id.*

Ariosa's business will likewise be decimated if a permanent injunction is issued. Within a period of thirty-nine months (from 2011 to 2014), Ariosa expended $40.2 million for research and development. *See* Ex. J at 70 (Dkt. No. 687-24 at 3). In addition, switching from Illumina sequencers would cost "an enormous amount of resources, time, and dollars." Trial Tr. at 1314:2-8. Additionally, Ariosa's claims concerning patent validity were not fully adjudicated until January 2018. At a minimum, based on the specific facts in the present case, the Court finds that the balance of the hardships is neutral and does not favor issuing an injunction.

4. Public interest

Plaintiffs argue that courts rarely find an injunction would disserve the public interest after a finding of infringement and that it is in the public interest for patent rights to be respected. Dkt. No. 666 at 12.

Defendant responds that there is a public interest in competition and consumers should be able to select from a number of different options when choosing a NIPT test. Dkt. No. 682 at 19-20. Defendant also contends there is a strong public interest where, as in here, the patentee does

not practice the patent. *Id*. at 20.

The Federal Circuit has stated that "the public interest nearly always weighs in favor of protecting property rights in the absence of countervailing factors, especially when the patentee practices his inventions." *Apple Inc. v. Samsung Elecs. Co.*, 809 F.3d 633, 647 (Fed. Cir. 2015). Consequently, protecting patent rights generally favors an injunction. Additionally, in most cases, a lack of competition does not demonstrate disservice of the public interest, at least when the competition is induced by the usage of infringed patented inventions. *Douglas Dynamics, LLC v. Buyers Products Co.*, 717 F.3d 1336, 1347 (2013). As a result, Ariosa's argument that there is a strong public interest in competition fails to convince this Court it should not grant a permanent injunction.

However, the Federal Circuit has noted that the public interest weighs in favor of the patentee "especially when the patentee practices his inventions." *Apple.*, 809 F.3d at 647. Here, the '794 patent is not currently in practice. Its primary iteration was in the now discontinued GoldenGate product. *See* Trial Tr. (1/8/2018) 133:21-25; Ex. I (McGrath Depo.) at 119:17-19, 121:18-22).

This Court is persuaded that the public interest will not be served by the issuance of a permanent injunction. *See Novozymes A/S v. Danisco A/S*, No. 10-CV-251-BBC, 2010 WL 3783682 (W.D. Wis. Sept. 24, 2010). In *Novozymes*, the defendants did not practice its patent or license the patent to a third party. *Id*. at *10. The court held that it would not permit a preliminary injunction because it is "inconsistent for plaintiffs to be arguing on one hand that the '723 patent represents an important new invention and then argue on the other hand that it should make no difference if no one is allowed to actually use it." *Id*.

Here, much like the defendants in *Novozymes* who did not practice or license their patent, Illumina does not currently practice the '794 patent. Consequently, this Court similarly holds that granting a permanent injunction could disserve the public interest or at the very most is neutral.

Plaintiffs' motion for a permanent injunction is DENIED.

VI. Plaintiffs' motion for an order of accounting and supplemental damages (Dkt. No. 662)

Plaintiffs have also filed a motion for an order of accounting and an award of supplemental damages. Dkt. No. 662. The Court DENIES plaintiffs' request. *Apple, Inc. v. Samsung Elecs. Co.*, 67 F. Supp. 3d 1100, 1118 (N.D. Cal. 2014) (denying plaintiff's request that the Court calculate and award supplemental damages pending the resolution of appeals).

CONCLUSION

For the foregoing reasons, the parties' motions are GRANTED IN PART and DENIED IN PART. In addition, the parties' pending motions to seal (Dkt. Nos. 684, 697) are GRANTED.

IT IS SO ORDERED.

Dated: July 19, 2018

SUSAN ILLSTON
United States District Judge